

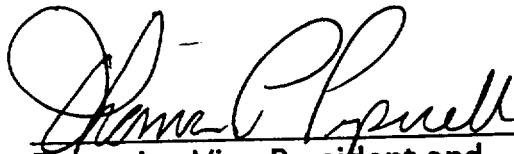
THE WILLIAM W. BACKUS HOSPITAL
NORWICH, CT.
BRACHYTHERAPY POLICY & PROCEDURE
MANUAL

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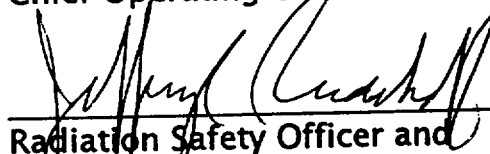
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THE WILLIAM W. BACKUS HOSPITAL
326 WASHINGTON STREET
NORWICH, CT 06360

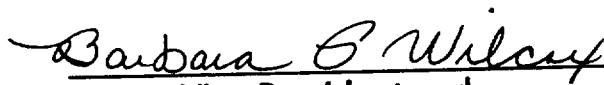
BRACHYTHERAPY POLICY AND PROCEDURE MANUAL
TRANSPERINEAL PROSTATE IMPLANT PROGRAM




Executive Vice President and
Chief Operating Officer
8/23/94
Date




Radiation Safety Officer and
Chairman of Radiation Safety Committee
8/22/94
Date



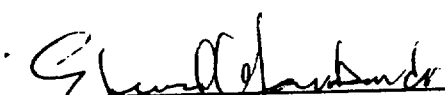
Senior Vice President and
Director of Nursing
8/23/94
Date



Vice President
8/22/94
Date



Associate Director of Surgical Services
8/23/94
Date



Diagnostic Imaging Manager
8/22/94
Date

ADOPTED: August 16, 1994
REVIEWED:
REVISED:

**THE WILLIAM W. BACKUS HOSPITAL
BRACHYTHERAPY POLICY AND PROCEDURE MANUAL**

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INTRODUCTION

The William-W. Backus Hospital has established a radiation seed implantation, or brachytherapy, program for the treatment of cancer of the prostate. The radiation material used in this program must be handled in accordance with the license issued by United States Nuclear Regulatory Commission. Pursuant to its federal license to operate the brachytherapy program, the Hospital must comply with regulations promulgated by the United States Nuclear Regulatory Commission. The purpose of this manual is to state the brachytherapy program policies and procedures that must be followed by all personnel involved with the program to ensure compliance with federal regulations and to ensure the safety and well-being of personnel and patients.

Currently, dosimetry and technical support for the service are provided under contract with Yale New Haven Hospital and the Yale University School of Medicine. As the licensee, The William W. Backus Hospital is responsible for all aspects of patient care and the handling of radioactive material for the program.

All personnel involved in this brachytherapy program are required to be familiar with the contents of this manual. The Radiation Safety Officer of The William W. Backus Hospital insures that all of the policies, procedures, and activities outlined in this manual are appropriate to the service and observed by the individuals involved in the program. Whenever necessary, the Radiation Safety Officer will initiate appropriate corrective measures to ensure the safety of patients and staff, or to comply with NRC regulations.

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PRE-HOSPITAL ACTIVITY

Once a potential patient with Prostate Cancer has been identified and evaluated by the referring physician, he is referred to the program's authorized user (Radiation Oncologist). The authorized user will then discuss the treatment options in detail with the patient.

After the patient has consented to the implant procedure, a "volume study" of the prostate gland is obtained using a transrectal ultrasound apparatus.

The authorized user will determine the target dose appropriate for the patient and the dosimetrist will prepare a computerized treatment plan. Once the authorized users selects the plan, a "written directive" (see Form BT 1) is prepared for the case and signed by the authorized user.

The case is then booked for surgery and the written directive sent to the hospital according to the Scheduling Procedure contained on page 1 of Section II of this manual.

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CREDENTIALING

- 1) **Surgeon:** The surgeon participating in the program shall be a member of the Hospital medical staff and will be required to have this procedure as a delineated privilege following the procedure in the current medical staff bylaws.
- 2) **Radiation Oncologist (authorized user):** The Radiation Oncologist shall be a member of the Hospital medical staff and will be required to have this procedure as a delineated privilege following the procedure in the current medical staff bylaws. In addition, the Radiation Oncologist must be listed on the Hospital's NRC Material License as an authorized user prior to participating in the procedure.
- 3) **Dosimetrist:** The Dosimetrist must provide his credentials to the Radiation Safety Officer and be approved for the procedure by The Radiation Safety Officer prior to participating in the program.
- 4) **Medical Physicist:** The Medical Physicist must provide his credentials to the Radiation Safety Officer and be approved for the procedure by the Radiation Safety Officer prior to participating in the program.

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TRAINING

Training shall be required for all new hires, for all program participants annually, and as appropriate when significant revisions are made to existing procedures. Training requirements are as follows (see Appendix 4 for sample training documents):

A. Contract Personnel

Radiation Oncologist
Dosimetrist
Medical Physicist

Prior to participating in a brachytherapy implant at Backus Hospital, the above named contract personnel will be responsible for reviewing and understanding the policies and procedures contained in this manual and for meeting with the Radiation Safety Officer.

B. Nuclear Medicine Personnel

All hospital employed Nuclear Medicine Technologists must become familiar with the policies and procedures contained in this manual. Additional training by the Medical Physicist of the Brachytherapy Program will include information regarding isotopes, standard dosages, proper handling of seeds, dose calibration procedures, and radiation safety. Prior to handling brachytherapy seeds or becoming involved in the program, the Radiation Safety Officer must approve their training.

C. Surgical Service Personnel

Surgical service personnel will be trained in all Radiation Safety requirements applicable to the program, the policies and procedures contained in this manual, the required patient identification steps, and postoperative patient education.

D. All inservice training shall be documented and maintained for all personnel participating in the brachytherapy program by the Radiation Safety Officer.

E. A list of personnel authorized by the Radiation Safety Officer to participate in the program will be kept in this manual.

- a) The Radiation Safety Officer (RSO) will approve changes to the list;
- b) The Radiation Safety Committee will review the list annually.

SECTION TITLE BRACHYTHERAPY PROCEDURE	PAGE	POLICY #
SUBJECT SCHEDULING PROCEDURE		
<p>The Surgical Services Scheduling Coordinator in the Department of Surgical Services shall:</p> <ol style="list-style-type: none"> 1. Schedule a brachytherapy implantation procedure upon receipt of a signed written directive (form BT-1), or a fax copy, for a patient from the authorized user and upon confirmation of the procedure by the attending surgeon. 2. After scheduling the procedure notify and send the written directive to the Nuclear Medicine Department at least five (5) days prior to the scheduled procedure. 3. Request the C-Arm and C-Arm Monitor for the scheduled procedure. 4. Verify that the Radiation Safety Officer will be available on the day of surgery. 		

SECTION TITLE BRACHYTHERAPY PROCEDURE	PAGE	POLICY #
SUBJECT ORDERING		
<ol style="list-style-type: none"> 1. A properly completed, signed written directive from the authorized user must be received by the Nuclear Medicine Department five (5) business days prior to the implant procedure. 2. Only the Radiation Safety Officer or a Nuclear Medicine Technologist are authorized to order brachytherapy seeds. 3. Upon receipt of a signed written directive, in the Nuclear Medicine Department, the Nuclear Medicine Technologist shall: <ol style="list-style-type: none"> a. Review the order to verify that it is written on the proper form, contains the required information including the patient name, isotope, number of seeds, activity per seed, range of total activity, seed calibration date, and the signature of the authorized user and that the activity per seed and total range of activity are within the authorized limits of the program as specified below. b. Brachytherapy seeds shall be ordered in a range of 0.3 to 0.6 millicuries per seed and shall not exceed a total activity of 60 millicuries for a single order for Iodine I-125. Acceptable ranges for Palladium P-103 are 0.4 to 0.8 millicuries per seed and the limit of total activity for a single order of Palladium P-103 is 95 millicuries. NOTE: The supplier (Medi-Physics or Theragenics) will not check to determine whether an order is within a specified dosage limit established by a particular buyer. 4. Prior to placing an order, the Nuclear Medicine Technologist shall obtain a new purchase order number from the Materials Management Department and write the number on the written directive. 		

5. Seeds may be ordered from:

PD-103
Theragenics Corporation
5325 Oakbrook Parkway
Norcross, GA 30093
(404) 381-8338
1-800-458-4372
FAX: (404) 381-8447

I-125 Seeds
Medi-Physics
2636 S. Clearbrook Drive
Arlington Hghts, IL 60005
1-800-633-4123
FAX: 1-800-826-9863

6. Seeds shall be sent from Theragenics Corporation or Medi Physics to:

ATTN: (Name of current Chief Nuclear Medicine Technologist)
Nuclear Medicine Department
William W. Backus Hospital
326 Washington Street
Norwich, CT 06360

7. The Nuclear Medicine Technologist shall place the order by telephone by reading the information from the written directive excluding patient identification, to the suppliers customer service representative. When applicable, a zero will precede the decimal point in the absence of an integer.

8. a. Prior to completion of the telephone order, a confirmation number should be issued by the supplier. The Nuclear Medicine Technologist shall write this confirmation number on the copy of the written directive along with the date the order was placed, and the name of supplier's representative.

b. Prior to completion of the order, the Nuclear Medicine Technologist will request the price per seed and the total invoice amount from the vendor. The amounts will be written on the written directive and compared to previous orders or to a predetermined vendor quotation.

9. A copy of the written directive, with patient identifiers removed, will be FAXED to the supplier to confirm the telephone order.

10. The Nuclear Medicine Technologist shall request that the supplier fax a supplier's verification of the order to Backus Hospital.

11. Upon receipt of the FAXED verification the NMT (Nuclear Medicine Technologist) will check the accuracy of the order by comparing the verification against the written directive.

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| <p>12. The written directive and the copy of the FAXED suppliers verification shall be placed in the Brachytherapy Record binder which shall be kept in the Nuclear Medicine Department.</p> <p>13. The Nuclear Medicine Technologist will notify the Radiation Safety Officer if any one of the following occurs:</p> <ul style="list-style-type: none">a. the written directive is incomplete or unsigned;b. requested dosage or activity exceeds order limits;c. the price per seed is not consistent with a bid quotation (if applicable) or within 5% of the amount per seed invoiced for previous orders;d. any follow-up call from the supplier regarding the order is received;e. a FAXED copy of the supplier's computer verification record is not received within 1 business day of the telephone order;f. the confirmation number is changed;g. fax verification conflicts with the written directive;h. any other deviation or ambiguity from policy or routine. | | |
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SECTION TITLE BRACHYTHERAPY PROCEDURE	PAGE	POLICY #
SUBJECT RECEIVING AND STORAGE		
<p data-bbox="240 310 511 338">RECEIPT OF ORDER</p> <ol data-bbox="240 359 1198 940" style="list-style-type: none"> <li data-bbox="240 359 1144 478">1. For deliveries during normal working hours, packages shall be delivered directly to the hot lab by the carrier and received by the Nuclear Medicine Technologist. <li data-bbox="240 499 1182 678">2. For deliveries outside of normal working hours, packages shall be placed in the hot lab by the Hospital security personnel who have been instructed to accept these packages, according to the memorandum issued by the Radiation Safety Officer on March 3, 1994. <li data-bbox="240 699 1198 940">3. The Nuclear Medicine Technologist shall be authorized to receive brachytherapy seeds in a range at 0.3 to 0.6 millicuries per seed and of a total activity for a single order up to 60 millicuries for Iodine I-125. Acceptable ranges for Palladium P-103 are 0.4 to 0.8 millicuries per seed and the limit of total activity for a single order of Palladium P-103 is 95 millicuries. <p data-bbox="240 961 846 989">OPENING PACKAGE AND CONFIRMING ORDER</p> <ol data-bbox="240 1010 1203 1598" style="list-style-type: none"> <li data-bbox="240 1010 1187 1171">1. The Nuclear Medicine Technologist, dosimetrist, and medical physicist are the only personnel authorized to open the package and shall open the package in the hot lab according to the following procedure. <li data-bbox="240 1192 1089 1220">2. Put on gloves to prevent hand contamination. <li data-bbox="240 1241 1203 1367">3. 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. <li data-bbox="240 1388 1203 1598">4. Measure and record the exposure rate from the package at one meter and at the package surface with a Geiger Mueller survey meter. If it is higher than the allowable readings specified below, stop and notify the Radiation Safety Officer. Maximum allowable readings for each type of package are: 		

LABEL	AT ANY POINT ON ACCESSIBLE SURFACE OF PACKAGE	AT THREE FEET FROM EXTERNAL SURFACE OF PACKAGE (TRANSPORT INDEX)
"Radioactive - White I"	0.5mR/hr	0
"Radioactive - Yellow II"	50mR/hr	1.0mR/hr
"Radioactive - Yellow III"	200mR/hr	10mR/hr
<p>5. Open package with the following precautionary steps:</p> <ul style="list-style-type: none"> a. remove the packing slip; b. check the packing slip against the physician's written directive to confirm that the material received is what was ordered; c. open the outer package following the suppliers instructions, if provided; d. open the inner package and verify that the contents (vial label, certificate of activity) agree with the packing slip; e. check the integrity of the final source container. Look for broken seals or vials, condensation, or discoloration of the packing material; f. if any discrepancy is noted upon receipt of the product, follow the instructions provided by the supplier in the packing insert and notify the Radiation Safety Officer; and g. if anything is other than expected, stop and notify the Radiation Safety Officer, immediately. <p>6. 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. This will be performed on the wipe test counter. The detection efficiency of this instrument will be posted on the side of the unit to enable easy conversion from wipe sample cpm to net dpm. Trigger level for the wipe test is 11,100 dpm per 100 square cm. Notify the Radiation Safety Officer and the supplier if this level is exceeded.</p>		

7. Check the written directive in the Brachytherapy Record to ensure that the material received is the material that was ordered by comparing the information on the vial label and the certificate of activity with the written directive. Report any discrepancy to the Radiation Safety Officer.
8. Monitor the packing material and the empty package for contamination with a Geiger-Mueller survey meter before discarding.
 - a. if contaminated, treat this material as radioactive waste;
 - b. if not contaminated, remove or obliterate the radiation labels before discarding in the in-house trash.
9. A record of the receipt must be made in the package receipt and monitor log (Form BT-5). This record must include:
 - a. date received;
 - b. Purchase Order number;
 - c. lot number of product;
 - d. activity in mCi's;
 - e. isotope;
 - f. chemical form;
 - g. supplier;
 - h. catalog number;
 - i. a statement that the package is in acceptable condition for receipt;
 - j. survey meter reading in mR/hr;
 - k. additional comments, if any; and
 - l. initials of the person monitoring the package.
10. The Nuclear Medicine Technologist will also record the required information into the Brachytherapy Sealed Source Inventory Log (see Form BT-3) . This log will be kept in the Brachytherapy Record along with the other brachytherapy documentation.

11. The Nuclear Medicine Technologist will notify the Radiation Safety Officer if any one of the following occurs:

- a. The order is not received within 2 business days of placement;
- b. the order does not agree with the written directive or confirmation number;
- c. the activity per seed or total activity of the order is above the limits authorized for the program;
- d. the leak test is above the maximum allowable ready;
- e. the wipe test is above the trigger level;
- f. any other deviation or ambiguity from policy or routine.

STORAGE

- 1. The vial of seeds contained in the lead pig will be removed from the hot lab and placed in the isotope storage room until the arrival of the physicist, or dosimetrist.

SECTION TITLE BRACHYTHERAPY PROCEDURE	PAGE	POLICY #
SUBJECT RELEASING ISOTOPES FOR USE		
<ol style="list-style-type: none"> 1. On the day of the scheduled procedure, the Nuclear Medicine Technologist shall remove the brachytherapy sealed source contained in the pig from the isotope storage room and place it in the hot lab so that the medical physicist or dosimetrist can perform the verification and test procedures listed below. 2. Handling Requirements: <ol style="list-style-type: none"> a. All seed handling shall be carried out behind suitable shielding of the right size and thickness to minimize the handler's radiation exposure. b. Forceps will be used to handle the implants and the maximum distance between handler and implants maintained. c. A film badge and a ring badge shall be worn by persons handling the implants. 3. The dosimetrist or medical physicist shall verify that the seed strength is what was prescribed for the patient by checking the certificate of activity and the vial label against the written directive. 4. The medical physicist or dosimetrist, using latex gloves, shall open the vial and perform a sealed source leak test, as follows: <ol style="list-style-type: none"> a. With the vial open, inside of the lead pig, insert a moistened cotton swab into the vial to obtain removable contamination by swabbing the seeds and the interior of the vial. Care should be taken not to misplace seeds. Carefully remove swab insuring that no seeds adhere. Remove the wipe sample to a low background area. Assay the wipe sample to determine if there is any removable radioactivity, using the wipe test counter. The detection efficiency of this instrument will be posted on the side of the unit to enable easy conversion from wipe sample cpm to net dpm. Trigger level for the wipe test is .005 microcuries or 11,100 dpm. 		

<p>5. The medical physicist or dosimetrist, in the presence of a Nuclear Medicine Technologist, will measure and record on the Brachytherapy Sealed Source Inventory Log the activity of no less than 4% of the brachytherapy seeds using the dose calibrator. To determine the number of seeds to be assayed, multiply the total number of seeds by 0.04 and round upwards to the nearest whole number. The dosimetrist and the Nuclear Medicine Technologist will sign or initial the record of the dose calibration. Using appropriate dose correction factors, the result must be within plus or minus 10% of the average certified activity listed on the supplier's certificate of activity. Discrepancies shall be reported immediately to the Radiation Safety Officer.</p> <p>6. The dosimetrist shall perform a calculation to determine the amount of decay, if any, between the assay date and the day of surgery. The input data for this calculation will be taken from the Certificate of Activity.</p> <p>7. The medical physicist or dosimetrist shall enter the quantity, seed strength, and total activity in the Brachytherapy Sealed Source Inventory Log and shall initial and date the entry.</p> <p>8. After completing the procedures as specified above the medical physicist or dosimetrist shall transport the pig containing the sealed source to the operating room.</p>		
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SECTION TITLE BRACHYTHERAPY PROCEDURE	PAGE	POLICY #
SUBJECT STERILIZATION AND PREPARATION OF SEEDS		
<p>The Brachytherapy Safety Nurse Coordinator or designee shall:</p> <ol style="list-style-type: none"> 1. Soak the B&K rectal probe, two parts of the stepping unit, and the ring badges. Make sure that you place the end of the rectal probe that attaches to the machine into a biohazard plastic bag to insure no water comes in contact with it. 2. Autoclave the B&K template, probe cradle, dosimetrist's acrylic needle holder, and both bars used to connect probe to B&K platform for ten minutes with the seed load. See #3. 3. Assure that the seeds are steam sterilized according to Theragenics or Medi-Physics recommended practices. <ol style="list-style-type: none"> a. A designated autoclave shall be used that meet the criteria and will not exceed 133° C (272 °F) and 30 PSI. b. Do not expose seeds to temperatures and pressures in excess of 138° C and 35 PSI c. A gauze covered lead pig secured with an elastic band shall be placed in a gauze lined, fine mesh flash pan during sterilization process to prevent the loss of seeds by way of the drain d. Place a Sterilizer Indicator strip and spore test monitor in flash pan. e. The autoclave shall run for 10 minutes at a temperature of 270° F, not to exceed 272° F f. The sterilizer shall be used for seed implants only by a person trained to follow the safety regulations for the handling of radioactive seeds. A film badge, lead apron and thyroid shield must be worn to place the seeds into the autoclave and to remove sterile seeds at the completion of the sterilization cycle. 		

<p>g. Record the patient name, Hospital number, time, temperature, and pressure on the surgical sterilization record located in Sub-Room D.</p> <p>4. The dosimetrist shall survey the seeds after sterilization to assure integrity of the seeds.</p> <p>5. After completing the sterilization process, the dosimetrist shall prepare the seeds for administration by loading the seeds into the implant applicator according to the treatment plan.</p>		
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SECTION TITLE BRACHYTHERAPY PROCEDURE	PAGE	POLICY #
SUBJECT PREPARATION PRIOR TO SURGERY		
<p>OPERATING ROOM (OR)</p> <ol style="list-style-type: none"> 1. A sign that meets the requirements of 10 CFR 20 shall be placed on the door of the OR suite indicating the prescence of radioactive materials. 2. Staff are to avoid walking from one side of the room to the door area after the case begins. This is to avoid a possible seed that may have dropped out onto the floor from leaving the room. 3. Don 2 pair of sterile gloves. The Set Up: <u>Cysto Table: sterile items only.</u> #22 cystoscope 12" lens cysto scope, bridge, water connector, light cord, flexible grasping forcep, camera drape, cysto tubing, grey rubber, 2 liter of water, probe cradle, template, and both bars for the B&K platform. (The surgeon will perform a cystoscopy at completion of case). <u>Covered mayo stand:</u> soaked B&K accessories and the rectal probe. Once you dry and put the stepping unit together, cover them with a sterile towel, then proceed to cover the rectal probe with the unsterile water balloon, and "o" ring using the extension set and a 30 cc syringe. Plug the probe into the machine. Turn on the machine, input the information on "P" pt. name, the hospital 6 digit number; on the second line enter the surgeons name, and the date, then push "Freeze". The probe should now operate. This is to insure that the probe is functioning properly. You may now turn the machine off until the surgeon is ready to use it. Change the outer pair of gloves before returning to the sterile Cysto Table. <u>Prep stand:</u> Prep set with Betadine solution, sterile gloves, prep sponges, sponge stick, and sterile towel. Renografin, toomey syringe, foley cath set (the surgeon will instill 50 cc of 1:1 renografin/sterile water into the bladder, and he will instill some renografin into the foley balloon, so he can visualize during procedure with c-arm). Clamp the catheter after filling and inform Anesthesia of the setup. 		

4. Dosimetrist's table:
Set up pack, towels, loading trough, jaret forceps, spacing material (2 packages), marking pen, bone wax, acrylic needle holder, manan needle sets (wait and ask the dosimetrist the amount he will need), collars with allen wrench (kept in the back of GU room in a plastic container).
5. Draping should be as follows:
Place a sheet under buttock which should cover platform, Ioban is to be applied to the perineum, leggings and sheet above. Apply a sterile clear sheet to the B&K panel prior to the start of the case. (This is kept outside of the Post Anesthesia Care Unit closet). The surgeon will place the probe in the cradle onto the stepping unit. He will change gloves and attach the sterile template to the stepping unit.
6. There is a 8 X 12 lead acrylic stand in the back of the GU room. Cover this with an X-ray cassette holder and place it on the dosimetrist's table to shield the manan needles containing seeds.
7. Write procedure as follows:
Brachytherapy I-125 Seed Implantation of the prostate with C-Arm and B&K ultrasound control, Cystoscopy on the Operative Procedure Record.
8. Under Implant:
Write all of the seed information including the log #, and the # of seeds on the Operative Procedure Record. Also note that the seeds were spore tested during the sterilization process. Appropriate information is found on the original lead shipping container that the dosimetrist delivers from the nuclear medicine department to the operating room. This information is written at the end of the procedure in the event a seed is recovered during the cystoscopy.
9. Count the Manan Needles and enter it on the count sheet.
10. Note the presence of the following Equipment:
B&K Equipment #699, C-Arm, Monitor, Olympus Camera, and Light Source. Also list the Geiger Mueller Survey Meter as present in the room and list its Model #, the type of GM, and calibration date.

SEEDS

1. The dosimetrist shall load the seeds into the implant applicator needles according to the treatment plan in the designated area of the G.U. Operating Room Suite.
2. The dosimetrist shall return the unused seeds, vial and certificate of activity to the Nuclear Medicine Department and complete the Brachytherapy Sealed Source Inventory Log

PERSONNEL

1. Traffic will be kept to a minimum. Staff not assigned to the case will not enter the operating room.
2. Radiation safety instructions shall be provided to all personnel dealing with or caring for the patient, prior to the implantation procedure including:
 - a. size and appearance of the radioactive implant;
 - b. safe handling of the implant;
 - c. shielding instructions in case of dislodged seed;
 - d. procedure for patient and visitor control, and;
 - e. procedure for notification of the Radiation Safety OfficerThis shall be noted under the comments section of the operative record.

PATIENT

1. The Brachytherapy Safety Nurse Coordinator shall:
 - a. complete the prospective assessment form;
 - b. verify the patients identity. (See Patient Identification)

DAY OF SURGERY

1. A sign that meets the requirements of 10 CFR 20 will be displayed on the doors of the OR Suite indicating the presence of radioactive materials.

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|---|--|--|
| <ol style="list-style-type: none"> 2. Radioactive labels are available for display on the patient's chart, PACU and the A-4 door. (supplies of these labels are kept in the back of the OR suite <u>or</u> in a box under the Brachytherapy desk in the conference room). 3. The Radiation oncologist (authorized user) must be present at the time that the patient is brought into the room for surgery. 4. Film badges shall be worn by all staff actively involved in the case. The surgeon shall wear a ring badge. Contract employees shall wear their personal monitoring devices. 5. Room Furniture: C-Arm, B&K machine and accessories, two extension cords, blue wedge mattress (kept in urology workroom), 3" tape to secure wedge to the OR table mattress, med table for loading seeds, sitting stools, cysto table, Olympus Cart, and IV Pole. 6. The scrub nurse shall assist the dosimetrist gown and glove. | | |
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SECTION TITLE BRACHYTHERAPY PROCEDURE	PAGE	POLICY #
SUBJECT PATIENT IDENTIFICATION		
<ol style="list-style-type: none"> 1. Day Before Surgery: The Brachytherapy Safety Nurse Coordinator shall check the patient's chart for a copy of his photograph identification and shall notify ext. 2374, Patient Registration, if the photograph identification is not present. 2. Immediately prior to surgery the Brachytherapy Safety Nurse Coordinator will verify the patient's identity by using the normal wrist band identification procedure, and by checking the patient's photograph identification. 		

SECTION TITLE BRACHYTHERAPY PROCEDURE	PAGE	POLICY #
SUBJECT VERIFICATION OF PRE-IMPLANT PROCESS		
<ol style="list-style-type: none"> 1. To verify the accuracy of the computerized treatment plan, the authorized user shall verify that the preplan input data used for the computer model match the information, including the patient's date of birth and the Backus medical record number, in the patient's record. 2. The authorized user must complete an authorized user checklist, (Form BT-2) prior to the insertion of the seeds. The authorized user may not delegate the responsibility to do the following to the dosimetrist or any other participant in the procedure. <ol style="list-style-type: none"> 1. ascertain patients identity; 2. verify that the current written directive and pretreatment plan is being use; 3. verify that the preplan input data used for the computer model match the information, including the patient's date of birth and the Backus medical record number, in the patient's record; 4. verify that the data on the written directive, vial label, and certificate of activity match; 5. verify that the implant application needles have been loaded accordingly; 6. review the document results of the dose calibration. <p>NOTE: The authorized user must visually compare the vial label and the certificate of activity against the written directive.</p>		

SECTION TITLE BRACHYTHERAPY PROCEDURE	PAGE	POLICY #
SUBJECT SEED IMPLANT PROCEDURE		
<ol style="list-style-type: none"> 1. The surgeon will implant the brachytherapy seeds under the direction of the authorized user according to the treatment plan. 2. Clinical modification shall be made to the treatment plan by the authorized user as necessary. 3. The actual location of the brachytherapy seeds shall be checked by fluoroscopy. 		

SECTION TITLE BRACHYTHERAPY PROCEDURE	PAGE	POLICY #
SUBJECT VERIFICATION OF ACTUAL IMPLANTATION OF SEEDS		
<ol style="list-style-type: none"> 1. An X-Ray localizing film or fluoroscope x-ray shall be taken to document the position of the implanted seeds. 2. The authorized user shall complete the post-operative written directive. 3. The Brachytherapy Safety Nurse Coordinator or designee shall verify that all records pertaining to the procedure are completed, signed, and in the patient's medical record. 		

SECTION TITLE BRACHYTHERAPY PROCEDURE	PAGE	POLICY #
SUBJECT POST-OPERATIVE SURVEY		
<p>ENVIRONMENT</p> <p>1. Immediately after implanting the sealed sources in a patient, the medical physicist or dosimetrist, shall make a radiation survey of the patient <u>and</u> the area of use to confirm that <u>no</u> seeds have been misplaced. A record of each survey shall be kept.</p> <p>PATIENT</p> <p>1. A Radiation Survey of the patient shall be taken and recorded on the Patient Seed Accountability Form (Form BT-10) using a Geiger Mueller survey meter. The record shall include:</p> <ul style="list-style-type: none"> a. date of survey; b. name of patient; c. dose rate of the patient expressed as millirem per hour and measured at one meter from the patient; d. the survey instrument used; and e. name of the person who made survey. <p>2. The medical physicist or dosimetrist shall verify that the patient radiation readings at body surface and at one meter are within the range for patient release according to 10 CFR 35 guidelines. (i.e. less than 5 mR/hr at 1 meter)</p>		

SECTION TITLE BRACHYTHERAPY PROCEDURE	PAGE	POLICY #
SUBJECT INVENTORY PROCEDURE (POST-OPERATIVE)		
<ol style="list-style-type: none"> 1. The unused seeds shall be accounted for by the medical physicist, authorized user, or the dosimetrist. The number of seeds returned plus the number of seeds implanted shall be checked to verify that it equals the amount initially delivered to Operating Room. 2. The Brachytherapy Sealed Source Inventory Log will include: <ol style="list-style-type: none"> a. number of sources returned to storage; b. total activity of sources returned to storage; c. patient's name; d. approximate activity per seed; e. room number; f. time/date returned to storage; g. number and activity of sources in storage after the return; and h. name of person returning sources to storage.. 3. The unused seeds shall be returned in a lead "PIG" to the Nuclear Medicine Technologist to be placed in storage for decay. 		

SECTION TITLE BRACHYTHERAPY PROCEDURE	PAGE	POLICY #
SUBJECT PATIENT EDUCATION (POST-OPERATIVE)		
<ol style="list-style-type: none"> 1. The Brachytherapy Safety Nurse Coordinator or her designee shall give the patient written and verbal instructions on radiation safety guidance before the patient is released from the hospital. The patient will sign the discharge form after the form has been explained and reviewed. (See Form # N-280). 		

SECTION TITLE BRACHYTHERAPY PROCEDURE	PAGE	POLICY #
SUBJECT PATIENT, STAFF, AND VISITOR SAFETY		
<p>1. Safety precautions shall be followed by patients, staff, and visitors, and shall be monitored by the staff on the patient's unit.</p> <p>a. A private room with private bath is required. An exception to this rule is that a room may be shared by two Brachytherapy patients receiving I-125. When the patient is in Post Anesthesia Care Unit, the patient will be restricted to the designated room.</p> <p>b. The patient's chart and room doors shall be posted with a radioactive materials sign that denotes source, dose, length of time and where visitors may stay in the patient's room, and that pregnant women and children under age of 18 are NOT ALLOWED unless the Radiation Safety Officer grants permission.</p> <p>e. All staff shall wear film badges when involved with the brachytherapy procedure intra-operatively or to render post-operative care.</p> <p>f. Monitoring of the foley catheter bag shall be done from the side of the bed. Avoid prolonged contact with patient's perineum. The patient's urine must be strained. A Long handled forcep and lead "PIG" will be available in the patient's room in the event of a dislodged seed. A urine collection container shall be available in the patient's room and stored until released by medical physicist or his designee.</p> <p>g. If a seed is found, by day shift staff personnel shall -NEVER TOUCH A SEED WITH THEIR BARE HANDS.</p> <p>- Pick up the seed with long handled forcep using care not to crush it;</p> <p>- place the seed into the lead "PIG", and</p> <p>- call ext. 4249 for instructions. After 3:30 PM , call security and they will transport the seed in the lead pig to the Nuclear Medicine Department hot lab.</p>		

If a seed dislodges on Evenings or Nights: after placing the seed into the lead "PIG", label it with the patient's name and unit number, call security and they will transport the seed to the Nuclear Medicine Hot Lab. Security will leave a note so to alert the day staff that a seed was recovered and who transported it to the hot lab.

h. Upon discharge, a bedlinen, trash, and room survey must be completed before any items are removed from room. The Patient Seed Accountability Form (Form BT-10) must be completed and signed by the surveyor.

i. Once the room is surveyed, it is now able to be cleaned by environmental services per hospital policy.

j. **CRUSHED SEED POLICY**

-If a crushed seed is found, the following policy shall be followed:

- using long handled forceps, place seed into the lead pig container. COVER WITH APPROPRIATE LEAD COVER PROVIDED.

- isolate the area the seed was found on by covering the area with a disposable blue pad, (absorbent are face down); and

- call the Radiation Safety Officer for instructions:

THIS AREA MUST BE ISOLATED, IF POSSIBLE, AND CONSIDERED A HAZARD AREA UNTIL THE RSO DETERMINES THE EXTENT OF THE EXPOSURE.

*Compliance with the above procedures will be monitored by the staff of each unit.

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PATIENT FOLLOW-UP REQUIREMENTS

- 1) As a follow up to seed implantation, the authorized user shall verify the source positions approximately 30 days after completing the procedure. The authorized user shall notify the Radiation Safety Officer of any clinically significant findings.
- 2) The Radiation Safety Officer shall be notified immediately by the patient's medical physician or surgeon of any medical emergency or death to a patient with Radioactive I-125 seed implants that occurs within one year of the date of insertion.

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DUTIES OF THE RADIATION SAFETY OFFICER (RSO)

Radiation Safety Officer

- A. The Hospital shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The Hospital, through the Radiation Safety Officer shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the Hospital's byproduct material program.
- B. The Radiation Safety Officer shall:
1. Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, misadministrations, and other deviations from approved radiation safety practice and implement corrective actions as necessary.
 2. Establish, collect in one binder or file, and implement written policy and procedures for:
 - (i) Authorizing the purchase of byproduct material;
 - (ii) Receiving and opening packages of byproduct material;
 - (iii) Storing byproduct material;
 - (iv) Keeping an inventory record of byproduct material;
 - (v) Using byproduct material safely;
 - (vi) Taking emergency action if control of byproduct material is lost;
 - (viii) Performing checks of survey instruments and other safety equipment;
 - (ix) Disposing of byproduct material;
 - (x) Training personnel who work in or frequent areas where byproduct material is used or stored;
 - (xi) Keeping a copy of all records and reports required by the Commission regulations, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations.
 3. Brief management once each year on the byproduct material program;
 4. Establish personnel exposure investigational levels that, when exceeded will initiate an investigation by the Radiation Safety Officer of the cause of the exposure.

5. Establish personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence;
6. Assist the Radiation Safety Committee in the performance of its duties;
7. Approve all personnel (verify training and credentials) involved in the program;
8. Approve all documents recommended by the contract service provider.
9. On the day of surgery, the Radiation Safety Officer or his designee shall be available, preferably in the Hospital, for the period one hour prior to and one hour following the actual implant procedure.

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DUTIES OF THE BRACHYTHERAPY SAFETY NURSE COORDINATOR

The Brachytherapy Safety Nurse Coordinator shall:

1. Be a member of the Radiation Safety Committee;
2. In the event that a policy is not adhered to or there is an inappropriate occurrence the brachytherapy safety nurse coordinator shall have a full and final authority to stop the procedure at any point and notify the RSO or the senior management representative in order to rectify the situation or cancel the case;
3. Be responsible for set up procedures and the coordinator of patient followup care.
4. Conduct training and orientation of surgical personnel involved in the surgical case;
5. Recommend changes to policies and procedures, as appropriate;
6. Verify that all personnel involved in the case are listed on the Radiation Safety Officers approved brachytherapy personnel list.
7. Review all changes of procedures and documents recommended by the contract service provider.
8. Review radiation safety instruction with the surgical team on the day of surgery, prior to the case.

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ROLE OF QUALITY ASSESSMENT AND IMPROVEMENT DEPARTMENT

- 1) The Quality Assessment and Improvement Department will perform chart reviews of all patients undergoing Brachytherapy. Review will include verifying that all required documents have been completed and are present in the patients' permanent record.
- 2) Records of the Quality Management Program review and evaluation and recommendations for corrective action, if any, will be presented to the Radiation Safety Committee and the Quality Assessment and Improvement Committee of the facility. The Radiation Safety Committee shall make modifications to the program as required.

A record of each Quality Management Program review and evaluation will be kept for three (3) years.

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QUALITY CONTROL TESTING

- 1) On a regular basis (at least, monthly) each treatment planning or dose calculating computer system used in preparation of brachytherapy treatment plans at this facility will undergo a quality control testing procedure to insure accuracy. A standardized test case for each type of brachytherapy procedure performed at the facility will be "run" through the computer system. Computer calculated dose will be compared to the test dose. Causes of any variation in dose in excess of three (3) percent will be investigated and corrected prior to the use of the computer system for patient dose calculations. Any outside vendor of brachytherapy services will also be held to these quality control parameters prior to provided services at this facility. The outside vendor must provide the quality control documentation on a quarterly basis to this facility.
- 2) Any deviation of test results must be immediately reported within 24 hours to the Radiation Safety Officer.

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QUALITY MANAGEMENT PROGRAM

QUALITY MANAGEMENT PROGRAM
FOR THE MEDICAL USE OF BYPRODUCT MATERIAL

HOSPITAL NAME: THE WILLIAM W. BACKUS HOSPITAL

ADDRESS: 326 Washington Street
Norwich, CT 06360

REVISION DATE: August 19, 1994

Requirement: Title 10, Code of Federal Regulations, Part 35
Section 35.32

The Radiation Safety Committee of The William W. Backus Hospital has adopted the following Quality Management Program to insure that its byproduct materials program is operated in accordance with NRC regulations and hospital policies and procedures.

A. PROGRAM DEFINITIONS

A.1. written directive: an order, in writing, for a specific patient, dated and signed by an authorized user of the facility prior to the administration of a radiopharmaceutical or radiation except as specified in the brachytherapy section of this definition, containing the following information:

- 1) For any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131: the dosage;
- 2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;
- 3) For brachytherapy:
 - (i) Prior to implantation: the radioisotope, number of sources, and source strengths; and
 - (ii) After implantation but prior to completion of the procedure; the radioisotope, treatment site, number of sources implanted, source strength, and total activity implanted.

A.2. prescribed dose: the quantity of a radiopharmaceutical activity as documented in either the written directive or the diagnostic clinical procedure manual and shall include:

-for brachytherapy: either the total source strength and exposure time or the total dose as documented in the written directive.

A.3. recordable event: the administration of:

-a radiopharmaceutical or radiation dose without a written directive when one was required,

-a radiopharmaceutical or radiation dose where a written directive was required without daily recording of each administered radiopharmaceutical dose or radiation dose in the appropriate record,

-a radiopharmaceutical dosage of I-125 or I-131 greater than 30 microcuries when both:

- the administered dose differs from the prescribed dose by more than 10%; and,
- the difference between the administered dose and the prescribed dose exceeds 15 microcuries.

-a therapeutic radiopharmaceutical dose other than I-125 or I-131 when the administered dose differed from the prescribed dose by more than 10%.

-a brachytherapy dose when the calculated administered dose differs from the prescribed dose by more than 10% of the prescribed dose.

A.4. misadministration: means the administration of:

-a radiopharmaceutical dose of I-131 or I-125 that is greater than 30 microcuries that:

-involves the wrong patient,

-when both the administered dose differs from the prescribed dose by more than 20% of the prescribed dose and the difference exceeds 30 microcuries,

-a therapeutic radiopharmaceutical dose other than I-131 or I-125 that:

- involves the wrong patient, wrong radiopharmaceutical, or route of administration,
- when the administered dose differs from the prescribed dose by more than 20%,
- a brachytherapy dose that:
 - involves the wrong patient, wrong radioisotope, or wrong treatment site (excluding permanent implant, seeds that were implanted in the correct site but migrated outside of the treatment site),
 - involves a leaking sealed source,
 - when for a temporary implant, one or more sealed sources are not removed upon the completion of the procedure,
 - when the calculated administered dose differs from the prescribed dose by more than 20%,
- a diagnostic radiopharmaceutical dose, other than quantities greater than 30 microcuries of I-131 and I-125 that:
 - involves the wrong patient, wrong radiopharmaceutical wrong route of administration or when the administered dose differs from the prescribed dose; and
 - when the dose to the patient exceeds 5 rem effective dose equivalent or 50 rem dose equivalent to any individual organ.

B. GENERAL REQUIREMENTS

- B.1 These general requirements apply to the administration of:
- a) Brachytherapy
 - b) A Diagnostic dose of I-131 or I-125 in excess of 30 microcuries
 - c) A Therapeutic dose of I-131 or I-125 in excess of 30 microcuries and less than 30 millicuries.
 - d) Radiopharmaceutical therapy other than b and c above
- B.2. Prior to administration, a written directive that is signed by a facility's authorized user is required. The original shall be kept in the patient's medical record after the order is placed. A copy shall be kept in Nuclear Medicine.
- B.3. The Nuclear Medicine Technologist (NMT) shall not initiate a diagnostic or a therapeutic procedure outlined above without a written directive or an acceptable oral directive as described in B.2.

- B.4. The nuclear medicine technologist (NMT) receiving the radioactive package from the supplier shall verify the authorized users written directive with the hard copy order confirmation and the manufacturers certificate of activity.
- B.5. The NMT will verify the activity is below the maximum allowable activity that can be received by a NMT and will consult the Radiation Safety Officer (RSO) if the maximum allowable level is surpassed.
- B.6. All individuals participating in the provision of a Diagnostic or Therapeutic radiopharmaceutical administration, or a brachytherapy procedure must provide documentation of their qualification to participate in the program and knowledge of the facilities policies and procedures. In addition, all such individuals shall be instructed in the principles of radiation safety appropriate to those individuals' use of byproduct material and in the facility's written quality management program.
- B.7. The NMT or Brachytherapy Safety Nurse Coordinator, as applicable, shall verify the patient's true identity prior to each administration requiring a written directive or an acceptable oral directive by more than one (1) method including but not limited to the following:

For inpatients:

- a) correct name per the wrist identification band,
- b) verbal request that the patient state his/her name.
(NOTE: do not ask "...is your name Mr. Smith...", but rather ask "... what is your name...")

For outpatients:

- a) ask the patient to state his/her name,
 - b) ask for written identification (ie: drivers license; birth certificate; social security card; etc.)
- B.8. The application of radiation or a radiation dose shall not occur unless positive identification of the patient is made. Inpatients without an identification bracelet cannot receive radioactive material.
- B.9. The final plan for any radiation therapy procedure and all related calculations with respect to brachytherapy will be reviewed by the dosimetrist to insure that the final plan is in accordance with the written directive.

- C. THE ADMINISTRATION OF DIAGNOSTIC QUANTITIES OF I-131 OR I-125 IN EXCESS OF 30 MICROCURIES:
- C.1. Prior to the removal from the hot lab and administration of diagnostic quantities of I-131 or I-125 in excess of 30 microcuries, the NMT that is assigned to the "hot lab" shall verify that the written directive is an order for specific named patient, is dated and signed by an authorized user and contains the radioisotope, dosage, and route of administration.
- C.2. If prior to the administration of the radiopharmaceutical, the authorized user decides to revise the original written directive, it may be done provided that the revised written directive is dated and signed by an authorized user prior to patient dose administration. An oral revision to the written directive is acceptable provided that any delay in treatment would jeopardize the patient's condition. Any oral revision to a written directive must be followed by written confirmation within 48 hours.
- C.3. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.
- C.4. The dose assay of radiopharmaceutical will be measured in a dose calibrator prior to the administration of the dose to confirm that the dosage measured compares to within +/- 10% of the dose intended by the written directive. Records of this dose assay will be maintained in accordance with the requirements of 10CFR 35.
- C.5. The "hot lab" NMT shall seek guidance from the chief NMT or the RSO if the written directive is confusing, ambiguous or not understood. DO NOT ASSUME.
- C.6. At the time of administration the authorized user is to sign or initial the patient's dose record and insure that the administration date; radiopharmaceutical; and radiation dose are properly recorded and conform to those specified in the written directive.
- C.7. Any deviation shall be immediately brought to the attention of the chief NMT and the radiation safety officer (RSO), before proceeding.

The RSO shall,

- a) Confer with the physician who prepared the written directive; the NMT involved; and, the facility's medical physicist to confirm that a deviation from the written directive did in fact occur.
 - b) With the assistance of the medical physicist, evaluate the underlying causes of the deviation.
 - c) Make recommendations and/or changes in departmental procedure to attempt to prevent the cause of this deviation in the future.
 - d) Report this occurrence to the radiation safety committee and the quality assurance committee of the facility.
- D. THE ADMINISTRATION OF A THERAPEUTIC QUANTITIES OF I-131 OR I-125 IN EXCESS OF 30 MICROCURIES AND LESS THAN 30 MILLICURIES:**
- D.1. Prior to the removal from the hot lab and administration of diagnostic quantities of I-131 or I-125 in excess of 30 microcuries and less than 30 millicuries, the NMT that is assigned to the "hot lab" shall verify that the written directive is an order for a specific named patient, is dated and signed by an authorized user and contains the radioisotope, dosage, and the route of administration.
 - D.2. If prior to the administration of the radiopharmaceutical, the authorized user decides to revise the original written directive, it may be done providing that the revised written directive is dated and signed by an authorized user prior to patient dose administration. An oral revision to the written directive is acceptable provided that any delay in treatment would jeopardize the patient's condition. Any oral revision to a written directive must be followed by written confirmation within 48 hours.
 - D.3. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.
 - D.4. The dose assay of the radiopharmaceutical will be measured in a dose calibrator prior to the administration of the dose to confirm that the dosage measured compares to within +/- 10% of the dose intended by the written directive. Records of this dose assay will be maintained in accordance with the requirements of 10CFR 35.

D.5. The "hot lab" NMT shall seek guidance from the chief NMT or the RSO if the written directive is confusing, ambiguous or not understood. DO NOT ASSUME.

D.6. At the time of administration the authorized user is to sign or initial the patient's dose record and insure that the administration date; radiopharmaceutical; and radiation dose are properly recorded and conform to those specified in the written directive.

D.7. Any deviation shall be immediately brought to the attention of the chief NMT and the radiation safety officer (RSO), before proceeding.

The RSO shall,

a) Confer with the physician who prepared the written directive; the NMT involved; and, the facility's medical physicist to confirm that a deviation from the written directive did in fact occur.

b) With the assistance of the medical physicist, evaluate the underlying causes of the deviation.

c) Make recommendations and/or changes in departmental procedure to attempt to prevent the cause of this deviation in the future.

d) Report this occurrence to the radiation safety committee and the quality assurance committee of the facility.

E. THE ADMINISTRATION OF ANY RADIOPHARMACEUTICAL THERAPY DOSE EXCLUSIVE OF DIAGNOSTIC DOSES OF I-125 AND I-131 GREATER THAN 30 MICROCURIES AND THERAPEUTIC DOSE OF I-125 AND I-131 GREATER THAN 30 MICROCURIES AND LESS THAN 30 MILLICURIES:

E.1. Prior to the administration of any radiopharmaceutical therapy, exclusive of diagnostic quantities of I-131 or I-125 in excess of 30 microcuries, and therapeutic doses of I-131 or I-125 in excess of 30 microcuries but less than 30 millicuries, the NMT shall verify the radioisotope and the dosage with that of the written directive. The NMT shall also verify that the written directive is an order for a specific patient is dated and signed by an authorized user and contains the radioisotope, dosage, and route of administration.

E.2. If prior to the administration of the radiopharmaceutical, the authorized user decides to revise the original written directive, it may be done providing that the revised written directive is dated and signed by an authorized user prior to patient dose administration. An oral revision to the written directive is acceptable provided that any delay in treatment

would jeopardize the patient's condition. Any oral revision to a written directive must be followed by written confirmation within 48 hours.

- E.3. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, and oral directive will be acceptable provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.
- E.4. The dose of radiopharmaceutical will be placed in a dose calibrator prior to the administration of the dose to confirm that the dosage measured compares to within +/- 10% of the dose intended by the written directive. Records of this dose assay will be maintained in accordance with the requirements of 10 CFR 35.
- E.5. The chief NMT shall seek guidance from the RSO if the written directive confusing, ambiguous or not understood. DO NOT ASSUME.
- E.6. At the time of administration the authorized user is to sign or initial the patient's dose record and insure that the administration date; radiopharmaceutical; and radiation dose are properly recorded and conform to those specified in the written directive.
- E.7. Only an authorized user may administer a therapeutic dose of a radiopharmaceutical.
- E.8. Any deviation shall be immediately brought to the attention of the radiation safety officer (RSO) before proceeding.

The RSO shall,

- a) Confer with the physician who prepared the written directive; the NMT involved; and, the facility's medical physicist to confirm that a deviation from the written directive did in fact occur.
- b) With the assistance of the medical physicist, evaluate the underlying causes of the deviation.
- c) Make recommendations and/or changes in departmental procedure to attempt to prevent the cause of this deviation in the future.
- d) Report this occurrence to the radiation safety committee and the quality assurance committee of the facility.

F. BRACHYTHERAPY:

- F.1. Prior to the start of a brachytherapy procedure, a written directive will be obtained from an authorized user of brachytherapy materials. This written directive will be specific for an individual patient in that the authorized user will write the patient's name as part of the directive. In addition to the patient's name, the written directive is to include the radioisotope, number of sources, the source strengths, type of implantation, and treatment site. The authorized user is to sign and date this written directive.
- F.2. If, however, because of the patient's condition, a delay in order to provide a written revision to the original written directive will jeopardize the patient's health, an oral revision will be allowed. All oral revisions must be documented immediately in the patient's record and a written directive must be signed and dated by the authorized user within 48 hours of the oral revision. If a delay in treatment will not jeopardize the patient's health, any revision to the original written directive must be in writing and signed and dated by an authorized user prior to the administration of the brachytherapy dose or the next brachytherapy fractional dose.
- F.3. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared and signed and dated by the authorized user within 24 hours of the oral directive.
- F.4. If brachytherapy sources or after loading templates have been implanted into the patient, x-ray localizing films or electronic recording of fluoroscopic X-Rays will be taken to document the position of the implanted sources or the position of "dummy" sources or fixed geometry applicators prior to inserting the sealed sources. These films or recordings will be reviewed by the authorized user.
- F.5. Once approved by the authorized user these films will be presented to the facility's dosimetrist who will prepare a treatment plan to show target organ dose and dose to surrounding tissue.
- F.6. The treatment plan will be prepared in accordance with the respective written directive and will be reviewed by the authorized user or a qualified physician under the supervision of the authorized user to determine satisfaction with the target organ dose.

- F.7. To verify the accuracy of the computerized treatment plan, the authorized user, or his designee, will perform a spot hand calculation of a few selected points. The computerized treatment plan and the spot hand calculations will be reviewed with the authorized user, signed and dated by the authorized user and made part of the patient's therapy record. For prostate implants, checking computer input data to verify that it matches the patient's identity may be substituted for this step.
- F.8. Prior to the start of a brachytherapy (seeds) procedure, the dosimetrist shall verify the radioisotope, source strength, number of sources, and total dose to be implanted with that specified in the written directive. In addition to any other verification steps, a sample seed shall be measured in a dose calibrator to confirm that the dosage measured compares to +/- 10% of the dose intended by the written directive. If sources were ordered from a supplier specifically for this implant, the dosimetrist shall also compare the certificate of activity and vial label prepared by the supplier of the sealed sources to that of the written directive to compare the radioisotope number of sources, source strength, and total activity to that so specified in the written directive.
- F.9. In addition, the prescribed radioisotope, number of sources, source strength, treatment site, method or route of administration, loading sequence, and total dose will be confirmed by the authorized user administering the brachytherapy treatment to verify agreement with the written directive, the treatment plan and manufacturer's certificate of activity.
- F.10 In addition, immediately prior to the administration of the brachytherapy sources, the authorized user will use a checklist to verify the following; patient identity, radioisotope, number of sources, source strength, total activity, treatment site, loading sequence, dosimetrist's hand calculation, if applicable, and dose calibration results.
- F.11 Immediately after implanting the sources, the authorized user will list the radioisotope, treatment site, number of sources implanted and total source strength. The authorized user shall date and sign this written directive. This written directive shall be part of the patients medical record.
- F.12 Any deviation shall be brought to the attention of the radiation safety officer (RSO).
- F.13 The dosimetrist shall seek guidance from the authorized user if the written directive is confusing, ambiguous or not understood. DO NOT ASSUME.

F.14 Only an authorized user named in the facility's NRC license may administer a brachytherapy procedure.

F.15 Any unintended deviation from the physician's written directive, as outlined above, will be brought to the attention of the RSO.

The RSO shall,

a) Confer with the physician who prepared the written directive; the NMT involved; and, the facility's medical physicist to confirm that a deviation from the written directive did in fact occur.

b) With the assistance of the medical physicist, evaluate the underlying causes of the deviation.

c) Make recommendations and/or changes in departmental procedure to attempt to prevent the cause of this deviation in the future.

d) Report this occurrence to the radiation safety committee and the quality assurance committee of the facility.

F.16 As a followup to implantation, the authorized user will periodically verify the source positions for each type of brachytherapy and shall notify the RSO of any clinically significant findings.

F.17 On a regular basis (at least, quarterly), each treatment planning or dose calculating computer system used in preparation of brachytherapy treatment plans at this facility will undergo a quality control testing procedure to insure accuracy. A standardized test case for each type of brachytherapy procedure performed at the facility will be "run" through the computer system. Computer calculated dose will be compared to test dose. Causes of any variation in dose in excess of three (3) percent will be investigated and corrected prior to the use of the computer system for patient dose calculations. Any outside vendor of brachytherapy services will also be held to these quality control parameters prior to provided services at this facility. The outside vendor must provide the quality control documentation on a quarterly basis to this facility.

G. QUALITY MANAGEMENT PROGRAM REVIEW:

G.1. Under the direction of the facility's RSO, the medical physicist shall conduct a review of the effectiveness of the

quality management program.

- G.2. Since the time of the last quality management program review, a listing of the patient procedures requiring a physician written directive will be obtained from the nuclear medicine department.
- G.3. A random sample of patient records from each modality performed by the institution (ie. radiopharmaceutical, brachytherapy, I-125, I-131) will be reviewed by the RSO and the medical physicist for compliance with the requirements of the quality management program. The sample size to be reviewed shall be as follows: 20% if the number of cases performed is greater than 100, 20 cases if the number of cases performed is between 20 and 100, and all if less than 20 cases are performed.
- G.4. If, however, there has been an instance of recordable event or misadministration since the time of the last program review, the sample size will be no less than 50% if the number of cases performed is greater than 100, 50 cases if the number of cases performed is between 50 and 100, and all if less than 50 cases are performed
- G.5. If during a program review an instance of recordable event or misadministration is uncovered, the sample size will be no less than 50% if the number of cases performed is greater than 100, 50 cases if the number of cases performed is between 50 and 100, and all if less than 50 cases are performed.
- G.6. In addition, the RSO and medical physicist will review all cases of misadministration - as defined by 10 CFR 35.2 - and all cases of recordable events - as defined by 10 CFR 35.2 - to determine the underlying cause of the event.
- G.7 This review and evaluation will occur at least once per twelve (12) months.
- G.8. If the results of this review indicate an error rate in excess of 2% of records reviewed, the QMP program will be reviewed on a quarterly basis for a period of one (1) year. If after, four such quarterly reviews, the facility's error rate has been reduced to below 2%, reviews will be placed on an annual basis.
- G.9. Records of the quality managements program review, evaluation and recommendations for corrective action will be presented to the radiation safety committee and the quality assurance committee of the facility. The radiation safety committee shall make modifications to the program as required.

A record of each QMP review and evaluation will be kept for a period of time equal to three (3) years.

G.10 Records of each written directive and the actual dose assayed prior to administration will be kept for a period of three (3) years in accordance with the requirements of 10 CFR 35.32(d). The information included in the radiopharmaceutical records will include the name of the radionuclide or radiopharmaceutical, the dose assayed, the date and signature or initial of the NMT who prepared the record.

G.11 In the event of a misadministration or the occurrence of a recordable event, the RSO shall direct an immediate program evaluation and investigation. In addition, the RSO or his designee shall notify the NRC of each misadministration in accordance with NRC regulations.

- a. The RSO and the medical physicist shall assemble the relevant facts concerning the misadministration or recordable event.
- b. The causes of the event shall be identified.
- c. The necessary corrective actions shall be determined.
- d. The staff involved shall be briefed concerning the causes of the event and corrective actions required.
- e. A formal report shall be prepared of the event for the NRC (if required); the radiation safety committee; and the quality assurance committee of the facility.
- f. The QMP will be modified if the results for program evaluation indicate that a change in policy and/or procedure is likely to reduce the chance of reoccurrence.
- g. Investigation and review of recordable events will be completed within thirty (30) days of occurrence of the event;

H. QUALITY MANAGEMENT PROGRAM RECORD KEEPING:

H.1. The facilities' nuclear medicine department will keep the following records for three (3) years:

- a) each written directive,
- b) review of each administered radiation dose or radiopharmaceutical where a written directive is required,
- c) a record of the assayed dose to include the name of the

radionuclide or radiopharmaceutical, the date, actual assayed dose, and the signature or initial of the individual who made the record,

- d) all written reports of the effectiveness of the quality management program including:

-records of each program review including the evaluations and findings of each review.
-record of each recordable event including the relevant facts and what corrective action, if any, was taken

H.2. The facilities' nuclear medicine department will keep the following records for five (5) years:

- a) All records and reports of misadministrations

-The records will contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

I. NRC NOTIFICATION OF MODIFICATIONS TO THE QUALITY MANAGEMENT PROGRAM:

I.1. Any modifications to the quality management program developed to increase the program effectiveness will be filed with the NRC within thirty (30) days of the effective date of the change.

Approved by:

Jeffrey C. Rudikoff, M.D.
Radiation Safety Officer

Date

THE WILLIAM W. BACKUS HOSPITAL
NORWICH, CT 06360
BRACHYTHERAPY POLICY AND PROCEDURE MANUAL

FORMS

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IV THERAPY AND RESPIRATORY THERAPY BRACHYTHERAPY INFORMATIVE INSERVICE

The hospital is now performing a new procedure to patients with prostate carcinoma. This involves inserting into the prostate gland, radioactive I-125 seeds percutaneously with needles by the surgeons with the assistance of a Yale Dosimetrist and a Radiation Oncologist.

It is important for you to know that these seeds are sealed sources and will not contaminate you. Their radiation levels are low and the patients are able to be released to the general public the same day of surgery. The medical reason they are kept here 6 to 7 hours is for the spinal anesthetic as well as monitoring the ability to void post-operatively. There is no radiation hazard to you. This inservice is to inform you and to make you aware.

The amount of time you would be in the room with the patient is small and the distance you will be from the patient's perineum is approximately 3 feet. Please know that the urine and blood from the patient is not radioactive. The inservicing of nursing staff is more involved as they will be rendering perineal care as well as monitoring their foley and straining their urine.

Please note that if you feel you would like more information, we have a 2 1/2 hour video available. This video is a combined effort of the surgeon, The W.W. Backus Hospital Brachytherapy Safety Nurse Coordinator, and the Yale radiation Safety Officer.

Also, if you ever have questions or concerns regarding any aspect of the procedure, please contact me and I will be happy to address them.

Remember TO MAINTAIN: TIME AND DISTANCE

Written by Sue Finkelstein, R.N., with the guidance of Michael Bohan, Health Physicist of Yale New Haven Hospital.

Approved by Stu Korchin, CMP

THE WILLIAM W. BACKUS HOSPITAL
AND
YALE NEW HAVEN HOSPITAL

Brachytherapy Pre-Plan Prescription
Prostate Seed Implant Program

WRITTEN DIRECTIVE

Patient Name _____

Backus medical record number _____

Patient Date of Birth _____

Isotope _____

Number of Seeds _____

Activity (mCi) per seed range _____

Total Activity mCi (Range) _____

Seed Calibration Date _____

Authorized User Signature

Date

**THE WILLIAM W. BACKUS HOSPITAL
DIRECTIONS FOR WRITTEN DIRECTIVE**

1. The written directive is filled out by the radiation oncologist (authorized user).
2. All lines must be filled in completely **signed and dated**.
3. A copy is sent to the Surgical Services Coordinator 5 business days prior to surgery to assist in booking the surgery.
4. A copy is sent to the Nuclear Medicine Department to order isotope sources.
5. The original is brought to the Hospital by the Radiation Oncologist (Authorized User) on the day of the procedure. This becomes part of the patient's permanent medical record at the end of the procedure.

THE WILLIAM W. BACKUS HOSPITAL
NORWICH, CT. 06360

AUTHORIZED USER'S CHECKLIST

To be filled out immediately prior to the administration of brachytherapy sources.

Authorized User
Confirmation Initials

- 1) Patient identity verified _____
- 2) Written directive present _____
- 3) Isotope _____
- 4) Number of seeds _____
- 4) Seed strength _____ mCi/seed _____
- 5) Total activity _____ mCi _____
- 6) Treatment site _____
- 7) Loading sequence prepared _____
- 8) Preplan input data including the patient's date of birth and Backus outpatient number, match the information listed on the volume study. _____
- 9) Dose calibration results _____
- 10) Isotope decay calculation has been properly completed _____

I affirm that I have personally and independently checked the initialed items above, prior to insertion of seeds in the patient.

Authorized User Signature

Date

Time

Addressograph

8/94

THE WILLIAM W. BACKUS HOSPITAL
DIRECTIONS FOR AUTHORIZED USER CHECK LIST

1. The form is filled out by the radiation oncologist (authorized user).
2. The Patients addressograph stamp must be placed in lower right hand corner.
3. The form is filled out prior to implantation of seeds in the Operating Room.
4. All lines must be completed and initiated.
5. The bottom of the form must be signed and dated by the Radiation Oncologist (Authorized User).
6. The form shall be filed in the patient's permanent medical record.

**THE WILLIAM W. BACKUS HOSPITAL
NUCLEAR MEDICINE DEPARTMENT
BRACHYTHERAPY SEALED SOURCE INVENTORY LOG**

Calibration Date	Receipt Date	Isotope	Confirmation Number	Lot Number	Patient Name

NO. OF SEEDS	X ACTIVITY EACH (mCi)	=	TOTAL ACTIVITY (mCi)
TOTAL ACTIVITY =			

54

		IN STORAGE			REMOVED			IMPLANTED IN PATIENT			RETURNED TO STORAGE			INITIALS OR SIGNATURE
DATE	TIME	NO.	mCi PER SEED	mCi TOTAL	NO.	mCi PER SEED	mCi TOTAL	NO.	mCi PER SEED	mCi TOTAL	NO.	mCi PER SEED	mCi TOTAL	

REMARKS:

ACTUAL ASSAYED SEED ACTIVITY:

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.

55 Written Directive has been compared to and is in agreement with the Certificate of Activity, Packing Slip and Vial Label.

Nuclear Medicine Technologist

Dosimetrist

Time and Date

Time and Date

**THE WILLIAM W. BACKUS HOSPITAL
DIRECTIONS FOR BRACHYTHERAPY SEALED SOURCE INVENTORY
LOG**

1. There are two responsible parties for the this form.
 - a. Nuclear Medicine Technologist receiving.
 - b. Dosimetrist

2. When the Nuclear Medicine Technologist receives Brachytherapy sources the following is filled out:
 - a. Top of Form
 1. calibration date
 2. receipt date
 3. isotope
 4. confirmation number
 5. log number
 6. patient name

 - b. Top Box
 1. Number of Sources X Activity of Each mCi = Total Activity mCi

 - c. Lower Box (Line #1)
 1. date
 2. time
 3. seeds in storage
 - number
 - mCi per seed
 - mCi total

3. Initial this box at the end of the column.

4. This form is then housed in the Nuclear Medicine Department in the Brachytherapy record until the day of the procedure.

5. On the day of the procedure the dosimetrist completes line number two of the form and initial the line.
6. The form remains in the Brachytherapy manual in the Nuclear Medicine Department.



The William W. Backus Hospital

Michael T. Moore, President and Chief Executive Officer

326 Washington Street, Norwich, Connecticut 06360
Phone (203) 889-8331

FAX COVER SHEET

Please Deliver The Following Pages As Soon As Possible

TO: _____ DATE: _____

ORGANIZATION: _____

SPECIAL INSTRUCTIONS: Please verify that this written directive matches the telephone order transmitted earlier and return a FAX copy of this order as it appears in your computer records within 24 hours. FAX # 823-6552

FROM: _____

Number of Pages (Including Cover Sheet): _____

If total number of pages were not received or are illegible, please call immediately (203)823-6391. Thank you.

OUR FAX NUMBER IS: (203)823-6342

**THE WILLIAM W. BACKUS HOSPITAL
FAX COVER SHEET AND SPECIAL INSTRUCTIONS**

1. The form is used by The Nuclear Medicine Technologist.
2. The fax cover sheet with preprinted special instructions typed on, it is used when faxing the Written Directive to the supplier for verification.

**THE WILLIAM W. BACKUS HOSPITAL
PRE-PLANNED I-125 SEEDS IN THE PROSTATE**

1. The form is filled out by the dosimetrist based on the computer data entered into the computerized treatment model.

**THE WILLIAM W. BACKUS HOSPITAL
PRE-PLANNED I-125 SEEDS IN THE PROSTATE**

1. The form is filled out by the dosimetrist based on the computer data entered into the computerized treatment model.

U)

THE WILLIAM W. BACKUS HOSPITAL
PRE-PLANNED I-125 SEEDS IN THE PROSTATE

TRANSAXIAL VIEWS

PATIENT NAME: _____

DATE: _____

5 + + + + + + +

4 + + + + + + +

 3 + + + **+** + + +

2 + + + + + + +

1 **+** **+** **+** **+** **+** **+** **+** **+**

A B C D E F G

5 + + + + + + +

4 + + + + + + +

 3 + + + **+** + + +

2 + + + + + + +

1 **+** **+** **+** **+** **+** **+** **+** **+**

A B C D E F G

5 + + + + + + +

4 + + + + + + +

 3 + + + **+** + + +

2 + + + + + + +

1 **+** **+** **+** **+** **+** **+** **+** **+**

A B C D E F G

5 + + + + + + +

4 + + + + + + +

 3 + + + **+** + + +

2 + + + + + + +

1 **+** **+** **+** **+** **+** **+** **+** **+**

A B C D E F G

5 + + + + + + +

4 + + + + + + +

 3 + + + **+** + + +

2 + + + + + + +

1 **+** **+** **+** **+** **+** **+** **+** **+**

A B C D E F G

5 + + + + + + +

4 + + + + + + +

 3 + + + **+** + + +

2 + + + + + + +

1 **+** **+** **+** **+** **+** **+** **+** **+**

A B C D E F G

TU WILLIAM W. BACKUS HOSPITAL
WRITTEN DIRECTIVE POST-OPERATIVE
LOADING PATTERN FOR TRANSRECTAL I-125 IMPLANTS

Patient Name: _____

Date of Implant: _____

Patient Number: _____

NEEDLE #	# OF SEEDS	LOAD PATTERN	PLAN HOLE	RX HOLE	PLANNED NEEDLE LOCATIONS ON TEMPLATE
1					5 - - - - -
2					4.5 - - - - -
3					4 - - - - -
4					3.5 - - - - -
5					3 - - - - -
6					2.5 - - - - -
7					2 - - - - -
8					1.5 - - - - -
9					1 - - - - -
10					A a B b C c D d E e F f G g
11					
12					<u>LOADING SUMMARY</u>
13					Number of Needles Loaded: _____
14					Number of Seeds Loaded: _____
15					Activity Per Seed (mCi): _____
16					Total Activity: _____
17					Assay Date: _____
18					Spacer Length: _____
19					
20					<u>IMPLANT SUMMARY</u>
21					Number of Needles Implanted: _____
22					Number of Seeds Implanted: _____
23					Calculated Activity Implanted (mCi): _____
24					Authorized User Signature and Date: _____
25					_____

**THE WILLIAM W. BACKUS HOSPITAL
WRITTEN DIRECTIVE POST-OPERATIVE AND LOADING PATTERN
FOR TRANSRECTAL I-125 PROSTATE IMPLANTS**

1. The dosimetrist is responsible for completing this form. The Authorized user is present and signs this form immediately following the procedure to verify the actual seed placement.
2. The form is filled out with patient's name, patient number and date of implant.
3. Each column is filled out from left to right according to where the seeds are actually placed.
4. The planned needle template is completed.
5. The loading and implant summary is completed.
6. The Authorized User verifies the form, signs and dates the bottom of the form.

THE WILLIAM W. BACKUS HOSPITAL
NORWICH, CONNECTICUT
TRAINING DOCUMENTATION

I _____ have completed the training program required to participate
Name

in the Brachytherapy Program. I have reviewed the Policy and Procedure Manual for the Program.

Signature

Date

Trainer

Date

8/94

Form # BT 8

BT.wp5

**THE WILLIAM W. BACKUS HOSPITAL
NORWICH, CONNECTICUT**

**APPROVED PARTICIPANTS LIST
RADIATION SAFETY OFFICER BRACHYTHERAPY PERSONNEL LIST**

TITLE	NAME	
Surgeon		
Radiation Oncologist		
Medical Physicist		
Dosimetrist		
Brachytherapy Safety Nurse Coordinator Designee		
Operating Room Nursing Staff		
Anesthesia Dept. MDs & Nurse Anesthetists		
Nuclear Medicine Technologists		

cc: Radiation Safety Officer
Brachytherapy Safety Nurse Coordinator

Signature

Date

8/94
Form #BT 9
BT.wp5

**THE WILLIAM W. BACKUS HOSPITAL
BRACHYTHERAPY I-125 SEED IMPLANT PROCEDURE
DISCHARGE INSTRUCTIONS**

1. The Discharge Instruction Form is stamped with the patient's addressograph plate in the Operating Room.
2. It is the responsibility of the Brachytherapy Safety Nurse Coordinator or their designee to assure that the patient has received discharge instructions.
3. The instructions may be given only by personnel trained to perform this function.
4. The Brachytherapy Safety Nurse Coordinator or their designee shall verify the form is signed, dated, and initialed appropriately.
5. The original of the discharge instructions are placed in the patient's chart.
6. The copy of the Discharge Instructions is given to the patient.

THE WILLIAM W. BACKUS HOSPITAL
BRACHYTHERAPY I-125 SEED IMPLANT PROCEDURE
DISCHARGE INSTRUCTIONS

1. Pink urine is normal for the first 24 hours after surgery. If you observe any clots, (semi-solid clusters of blood) or deep cranberry colored urine, contact Dr. Friedman.
2. For the next twenty-four hours after discharge, we ask that you strain your urine with the strainer provided. If a seed is found, do the following:
 - a. Pick up the seed with a disposable spoon. Do not touch the seed with your hands.
 - b. Place the seed into a small piece of aluminum foil.
 - c. Place this foil wrapped seed into a glass jar with a lid.
 - d. Call the Nuclear Medicine Department 889-8331 extension 4249 from 7AM until 3:30PM. If a seed is recovered after this time or on the week-end, the seed should remain in the lid covered jar, making sure it is out of reach of others, until Monday.
3. **NOTIFY DR. FRIEDMAN:**
 - a. For pain and bleeding under the scrotum.
 - b. If you are unable to pass your urine for 6 hours after discharge home, or have a fullness in your bladder.
4. **LIMITATIONS AS FOLLOWS:**
 - a. Do not drive for the first 24 hours.
 - b. Avoid heavy lifting for 2 days. After this time you may resume light activities unless otherwise indicated by Dr. Friedman.
 - c. As a precaution, avoid close contact with pregnant women.
 - d. As a precaution, avoid holding a child for any length of time on your lap for 6 months.
5. You may resume sexual activity after 2 weeks. A condom must be used for one month after the procedure in the unlikely event that a seed is dislodged via the ejaculate.
6. **CALL DR. FRIEDMAN FOR AN APPOINTMENT**
I HAVE RECEIVED AND CLEARLY UNDERSTAND THE INSTRUCTIONS GIVEN.

PATIENT/SIGNIFICANT OTHER/SIGNATURE _____ DATE _____ RN'S INIT. _____
BRACHYTHERAPY I-125 SEED IMPLANT ADDRESSOGRAPH
DISCHARGE INSTRUCTIONS
FORM #N-250 NEW 2/54

**THE WILLIAM W. BACKUS HOSPITAL
PATIENT SEED ACCOUNTABILITY FORM**

1. Permanent Implant Notice, patient's chart copy is attached to the top of the sheet by the Brachytherapy Safety Nurse Coordinator.
2. The Caution Radioactive Material Sign is attached in the second box and verified by the Brachytherapy Safety Nurse Coordinator.
3. The box title Patient's name is filled out in its entirety by the Dosimetrist while the patient is in the Post Anesthesia Care Unit (PACU). See page 21 of the Brachytherapy Policy and Procedure manual.
4. The box titled Visitor Limits is filled out by the Dosimetrist or Health Physicist when the patient is in the Post Anesthesia Care Unit (PACU).
5. The box titled Radiation Safety Surveys:
 - a. All of the lines after a date are filled out completely.
 - b. The following section of this form is filled out by approved Geiger Mueller Ludlum 3 Monitor Staff Personnel from the Operating Room, Post Anesthesia Care Unit (PACU), Critical Care Unit (CCU), or Patient Unit Staff (A-4);
 - date
 - time
 - area
 - mr/hr
 - meter
 - initials

Attach Permanent Implant Notice Here
(Patient's Chart Copy)

Attach Patient Contains Radioactive
Materials Notice Here
(Door to Patient's Room Copy)

CAUTION: This Patient Contains Radioactive Materials

Patient Name: _____ Patient Unit Number: _____ Patient Room Number: _____ Date & Time Inserted: _____ Area Inserted: _____ Radioisotope: _____ Type of Source: _____ Number of Sources: _____ Activity/Source (mCi): _____ Total Activity (mCi): _____ Dose Rate at 1 meter: _____ mR/hr Surveyor Initials: _____ Survey Meter: _____ Date & Time Surveyed: _____	Visitor Limits: <input type="checkbox"/> No Radiological Restrictions <input type="checkbox"/> Special Instructions:					
	Radiation Safety Surveys:					
Survey all foley catheters, linen, trash and the patient's room with a Geiger counter before patient release.						
IN THE EVENT OF AN EMERGENCY, CONTACT RADIATION SAFETY AT 785-2950 OR DIGITAL PAGE NUMBERS 340-3255 OR 340-3067						
Copies: Chart (White); Kardex (Blue); Room (Yellow); Physics (card)						

WILLIAM BACKUS HOSPITAL
 PATIENT SEED ACCOUNTABILITY FORM
 Form # BT-10

REV 20-Jun-94
 08/94

**THE WILLIAM W. BACKUS HOSPITAL
INTRA-OPERATIVE RECORD OF NURSING CARE**

1. This form is the responsibility of the Brachytherapy Safety Nurse Coordinator or their designee.
2. The form is filled out according to Operating Room Policy and Procedure, along with:
 - a. Under the Graphs, Implants, and Prosthesis section, the following information is documented;
 - From the Shipping Vial
 - type of radioactive implant;
 - seed strength;
 - total activity;
 - assay date.
 - The location of implant
 - The number of seeds implanted
 - Documentation of spore testing
 - b. Under comments the names of the Radiation Oncologist, Health Physicist, X-Ray Technician, and any other approved participants are written. Indicate a review of Radiation Safety Instructions with the surgical team on the day of surgery prior to the case.

SURGEON: _____ ASSISTANT: _____ DATE: _____ O.R.F.M. _____
 MAJOR MINOR
 SCRUB: _____ WOUND CLASSIFICATION: _____
 CIRCULATOR: _____ PATIENT IN: _____
 ANES: GEN LOC TOP SPINAL BLOCK: M.A.C. OTHER: BY: _____ START: _____
 PREOPERATIVE DIAGNOSIS: _____ FINISH: _____
 OPERATIVE PROCEDURE: _____ PATIENT OUT: _____
 POSTOPERATIVE DIAGNOSIS: SAME DISCHARGED TO: P.A.C.U.
 I.C.U. P.T. UNIT

COMPLICATIONS: _____
 POSITION: SUPINE PRONE JACKKNIFE LITHOTOMY LATERAL LT. RT. ANDREWS FRAME WILSON FRAME OTHER:
 POS. AIDE & PLACEMENT: SEATBELT ARMS ABDUCTED ON PADDED ARMBOARD: RT. LT.

SKIN PREP: NONE POVIDONE IODINE: SCRUB SOLUTION HIBICLENS PHISOX HYDROGEN PEROXIDE ALCOHOL 70%
 2% TR. IODINE ACETONE OTHER: BY: _____

CAUTERY: N.A. <input type="checkbox"/>	GROUND SITE:	TOURNIQUET: N.A. <input type="checkbox"/> BY: _____			ESMARK: _____			
NOT ACTIVATED: <input type="checkbox"/>	COAG.	CUT	BLEND	PRESSURE	TIME UP	TIME DOWN	EXTREMITY	TYPE & NUMBER
MONOPOLAR #								
BIPOLAR #								
DIATHERMY #								

SKIN CONDITION POST REMOVAL

COUNTS: C (CORRECT) U (UNRESOLVED) N.A. (NOT APPLICABLE) IF UNRESOLVED XRAY TAKEN? YES NO	CIRC. SIGN/SCRUB NAME			OTHER ACTION TAKEN			IRRIGATION: N.A. <input type="checkbox"/>		
	SPONGE	SHARPS	INSTRUMENT				TYPE	AMOUNT	LOCATION
1.									
2.									
3.									
4.									
5.									

EQUIPMENT: _____
 GRAFTS, IMPLANTS, PROSTHESES: N.A.
 SIZE TYPE SERIAL # / LOT # LOCATION

DRAIN/PACK: N.A.

G.U. CATH: N.A. FROM PT. UNIT REMOVED OUTPUT DISC. OR. _____ ML. G.U. CATH. _____ FR. FOLEY c. _____ ML. BAL. URIMETER BY: _____
 SPECIMENS: N.A.

COMMENTS: _____

POST. OP. REPORT TO: _____ PATIENT INFORMATION: RN SIGNATURE _____
 THE WILLIAM W. BACKUS HOSPITAL
 INTRAOPERATIVE RECORD OF NURSING CARE
 FORM OR01 (REVISED 6/80, 9/85, 10/87, 12/89, 4/90)

THE WILLIAM W. BACKUS HOSPITAL
NORWICH, CT 06360
BRACHYTHERAPY POLICY AND PROCEDURE MANUAL

GLOSSARY OF TERMS

Address of Use means the building or buildings that are identified on the license and where byproduct material may be received, used, or stored.

ALARA (as low as reasonably achievable) means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical: (1) Consistent with the purpose for which the licensed activity is undertaken. (2) Taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and (3) In relation to utilization of nuclear energy in the public interest.

Area of Use means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing byproduct material.

Authorized user means a physician dentist, or podiatrist who is identified as an authorized user on a Commission or Agreement State license that authorizes the medical use of byproduct material.

Brachytherapy source means an individual sealed source or a manufacturer-assembled source train that is not designed to be disassembled by the user.

Dedicated check source means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

Diagnostic clinical procedures manual means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedure; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

Management means the chief executive officer or that person's delegates.

Medical Institution means an organization in which several medical disciplines are practice.

Medical use means the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings in the practice of medicine in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

Ministerial change means a change that is made, after ascertaining the applicable requirements, by persons in authority in conformance with the requirements and without making a discretionary judgment about whether those requirements should apply in the case at hand.

Misadministration see Page 2 of the Quality Management Program.

NMT means Nuclear Medicine Technologist.

Physician means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

Prescribed dosage means the quantity of radiopharmaceutical activity as documented: (1) In a written directive; or (2) Either in the diagnostic clinical, procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

Prescribed dose means (1) for gamma stereotactic radiosurgery, the total dose as documented in the written directive; (2) for teletherapy, the total dose and dose per fraction as documented in the written directive; or (3) for brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive.

Radiation Safety Officer (RSO) means the individual identified as the Radiation Safety Officer on a Commission license.

Recordable event means the administration of: (1) A radiopharmaceutical or radiation without a written directive where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record; (2) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131 when both; (i) The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and (ii) the difference between the administered dosage and prescribed dosage exceeds 15 microcuries; (3) a therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage; (4) a teletherapy radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose; or (5) a brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

Sealed source means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

Written Directive see page 1 of the Quality Management Program.

**THE WILLIAM W. BACKUS HOSPITAL
NORWICH, CT 06360
BRACHYTHERAPY POLICY AND PROCEDURE MANUAL**

**NUCLEAR REGULATORY COMMISSION
RULES AND REGULATIONS PART 35
MEDICAL USE OF BYPRODUCT MATERIAL**

**PART
35**

MEDICAL USE OF BYPRODUCT MATERIAL

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57 FR 55062

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 66 Stat. 1242, as amended (42 U.S.C. 5041).

Subpart A—General Information

§ 35.1 Purpose and scope.

This part prescribes requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this part are in addition to, and not in substitution for, others in this chapter. The requirements and provisions of Parts 19, 20, 21, 30, 71, and 170 of this chapter apply to applicants and licensees subject to this part unless specifically exempted.

51 FR 36924

§ 35.2 Definitions.

"Address of use" means the building or buildings that are identified on the license and where byproduct material may be received, used, or stored.

"Agreement State" means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

"ALARA" (as low as reasonably achievable) means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical:

(1) Consistent with the purpose for which the licensed activity is undertaken.

(2) Taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and

(3) In relation to utilization of nuclear energy in the public interest.

"Area of use" means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing byproduct material.

"Authorized user" means a physician, dentist, or podiatrist who is identified as an authorized user on a Commission or Agreement State license that authorizes the medical use of byproduct material.

"Brachytherapy source" means an individual sealed source or a manufacturer-assembled source train that is not designed to be disassembled by the user.

"Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

"Dental use" means the intentional external administration of the radiation from byproduct material to human beings in the practice of dentistry in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

"Dentist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

Diagnostic clinical procedures manual means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

"Management" means the chief executive officer or that person's delegate or delegates.

"Medical Institution" means an organization in which several medical disciplines are practiced.

"Medical use" means the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings in the practice of medicine in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

"Ministerial change" means a change that is made, after ascertaining the applicable requirements, by persons in authority in conformance with the requirements and without making a discretionary judgment about whether those requirements should apply in the case at hand.

Misadministration means the administration of:

(1) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131:

(i) Involving the wrong patient or wrong radiopharmaceutical, or

(ii) When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries.

(2) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:

(i) Involving the wrong patient, wrong radiopharmaceutical, or wrong route of administration; or

(ii) When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

(3) A gamma stereotactic radiosurgery radiation dose:

(i) Involving the wrong patient or wrong treatment site; or

(ii) When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.

(4) A teletherapy radiation dose:

(i) Involving the wrong patient, wrong mode of treatment, or wrong treatment site;

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

(iii) When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or

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

(5) A brachytherapy radiation dose:

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

(ii) Involving a sealed source that is leaking;

(iii) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

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

(6) A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, both:

(i) Involving the wrong patient, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

(ii) When the dose to the patient exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ.

"Mobile nuclear medicine service" means the transportation and medical use of byproduct material.

"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

"Physician" means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

"Podiatric use" means the intentional external administration of the radiation from byproduct material to human beings in the practice of podiatry in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

"Podiatrist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

Prescribed dosage means the quantity of radiopharmaceutical activity as documented:

- (1) In a written directive; or
- (2) Either in the diagnostic clinical-procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

Prescribed dose means:

- (1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
- (2) For teletherapy, the total dose and dose per fraction as documented in the written directive; or
- (3) For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive.

"Radiation Safety Officer" means the individual identified as the Radiation Safety Officer on a Commission license.

Recordable event means the administration of:

- (1) A radiopharmaceutical or radiation without a written directive where a written directive is required;
- (2) A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;
- (3) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131 when both:
 - (i) The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and
 - (ii) The difference between the administered dosage and prescribed dosage exceeds 15 microcuries;
- (4) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;
- (5) A teletherapy radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose; or
- (6) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

"Sealed source" means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

"Teletherapy physicist" means the individual identified as the teletherapy physicist on a Commission license.

"Visiting authorized user" means an authorized user who is not identified as an authorized user on the license of the licensee being visited.

Written directive means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in paragraph (6) of this definition, containing the following information:

- (1) For any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131: the dosage;
- (2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;
- (3) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;
- (4) For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;
- (5) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or
- (6) For all other brachytherapy:
 - (i) Prior to implantation: the radioisotope, number of sources, and source strengths; and
 - (ii) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

§ 35.5 Maintenance of records.

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

§ 35.8 Information collection requirements: OMB approval.

(a) The Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements in this part under control number 3150-0010.

(b) The approved information collection requirements contained in this part appear in §§ 35.12, 35.13, 35.14, 35.21, 35.22, 35.23, 35.27, 35.29, 35.31, 35.50, 35.51, 35.53, 35.59, 35.60, 35.61, 35.70, 35.80, 35.92, 35.204, 35.205, 35.310, 35.315, 35.404, 35.406, 35.410, 35.415, 35.608, 35.610, 35.615, 35.630, 35.632, 35.634, 35.636, 35.641, 35.643, 35.645, and 35.647.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved as follows:

- (1) In § 35.12, Form NRC-313 is approved under control number 3150-0120.

(d) OMB has assigned control number 3150-0171 for the information collection requirements contained in §§ 35.32 and 35.33.

§ 35.11 License required.

(a) A person shall not manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for medical use except in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraph (b) of this section.

(b) An individual may receive, possess, use, or transfer byproduct material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in § 35.25, unless prohibited by license condition.

§ 35.12 Application for license, amendment, or renewal.

(a) If the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, any person may apply.

(b) An application for a license for medical use of byproduct material as described in §§ 35.100, 35.200, 35.300, 35.400, and 35.500 of this part must be made by filing an original and one copy of Form NRC-313, "Application for Materials License." For guidance in completing the form, refer to the instructions in the most current versions of the appropriate Regulatory Guides. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

(c) An application for a license for medical use of byproduct material as described in § 35.600 of this part must be made by filing an original and one copy of Form NRC-313. For guidance in completing the form, refer to the instructions in the most current version of the appropriate Regulatory Guide. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

(d) For copies of regulatory guides, application forms, or to submit an application or an amendment request, refer to § 30.6 of this chapter.

§ 35.13 License amendments.

A licensee shall apply for and must receive a license amendment:

(a) Before it receives or uses byproduct material for a clinical procedure permitted under this Part but not permitted by the license issued pursuant to this part;

(b) Before it permits anyone, except a visiting authorized user described in § 35.27, to work as an authorized user under the license;

(c) Before it changes Radiation Safety Officers or Teletherapy Physicists;

(d) Before it orders byproduct material in excess of the amount, or radionuclide or form different than authorized on the license; and

(e) Before it adds to or changes the areas of use or address or addresses of use identified in the application or on the license.

§ 35.14 Notifications.

A licensee shall notify the Commission by letter within thirty days when an authorized user, Radiation Safety Officer, or Teletherapy Physicist permanently discontinues performance of duties under the license or has a name change, or when the licensee's mailing address changes. The licensee shall mail the report to the appropriate address identified in § 30.6 of this chapter.

§ 35.18 License issuance.

The Commission shall issue a license for the medical use of byproduct material for a term of five years if:

(a) The applicant has filed Form NRC-313 "Application for Materials License" in accordance with the instructions in § 35.12;

(b) The applicant has paid any applicable fee as provided in Part 170 of this chapter;

(c) The Commission finds the applicant equipped and committed to observe the safety standards established by the Commission in this Chapter for the protection of the public health and safety; and

(d) The applicant meets the requirements of Part 30 of this chapter.

§ 35.19 Specific exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. The Commission will review requests for exemptions from training and experience requirements with the assistance of its Advisory Committee on the Medical Uses of Isotopes.

Subpart B—General Administrative Requirements**§ 35.20 ALARA program.**

(a) Each licensee shall develop and implement a written radiation protection program that includes provisions for keeping doses ALARA.

(b) To satisfy the requirement of paragraph (a) of this section:

(1) At a medical institution, management, the Radiation Safety Officer, and all authorized users must participate in the program as requested by the Radiation Safety Committee.

(2) For licensees that are not medical institutions, management and all authorized users must participate in the program as requested by the Radiation Safety Officer.

(c) The program must include notice to workers of the program's existence and workers' responsibility to help keep dose equivalents ALARA, a review of summaries of the types and amounts of byproduct material used, occupational doses, changes in radiation safety procedures and safety measures, and continuing education and training for all personnel who work with or in the vicinity of byproduct material. The purpose of the review is to ensure that licensees make a reasonable effort to maintain individual and collective occupational doses ALARA.

§ 35.21 Radiation Safety Officer.

(a) A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program.

(b) The Radiation Safety Officer shall:

(1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, misadministrations, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Establish, collect in one binder or file, and implement written policy and procedures for:

(i) Authorizing the purchase of byproduct material;

(ii) Receiving and opening packages of byproduct material;

(iii) Storing byproduct material;

(iv) Keeping an inventory record of byproduct material;

(v) Using byproduct material safely;

(vi) Taking emergency action if control of byproduct material is lost;

(vii) Performing periodic radiation surveys;

(viii) Performing checks of survey instruments and other safety equipment;

(ix) Disposing of byproduct material;

(x) Training personnel who work in or frequent areas where byproduct material is used or stored;

(xi) Keeping a copy of all records and reports required by the Commission regulations, a copy of these regulations, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations.

(3) Brief management once each year on the byproduct material program;

(4) Establish personnel exposure investigational levels that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure;

(5) Establish personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence;

(6) For medical use not at a medical institution, approve or disapprove minor changes in radiation safety procedures that are not potentially important to safety with the advice and consent of management; and

(7) For medical use at a medical institution, assist the Radiation Safety Committee in the performance of its duties.

§ 35.22 Radiation Safety Committee.

Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of byproduct material.

(a) Each Committee must meet the following administrative requirements:

(1) Membership must consist of at least three individuals and must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.

(2) The Committee must meet at least quarterly.

(3) To establish a quorum and to conduct business, at least one-half of the Committee's membership must be present, including the Radiation Safety Officer and the management's representative.

(4) The minutes of each Radiation Safety Committee meeting must include:

- (i) The date of the meeting;
- (ii) Members present;
- (iii) Members absent;
- (iv) Summary of deliberations and discussions;
- (v) Recommended actions and the numerical results of all ballots; and
- (vi) ALARA program reviews described in § 35.20(c).

(5) The Committee must promptly provide each member with a copy of the meeting minutes, and retain one copy for the duration of the license.

(b) To oversee the use of licensed material, the Committee must:

(1) Review recommendations on ways to maintain individual and collective doses ALARA;

(2) Review, on the basis of safety and with regard to the training and experience standards in Subpart J of this part, and approve or disapprove any individual who is to be listed as an authorized user, the Radiation Safety

Officer, or a Teletherapy Physicist before submitting a license application or request for amendment or renewal;

(3) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove minor changes in radiation safety procedures that are not potentially important to safety and are permitted under § 35.31 of this Part;

(4) Review quarterly, with the assistance of the Radiation Safety Officer, a summary of the occupational radiation dose records of all personnel working with byproduct material;

(5) Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving byproduct material with respect to cause and subsequent actions taken; and

(6) Review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

§ 35.23 Statements of authority and responsibilities.

(a) A licensee shall provide the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, sufficient authority, organizational freedom, and management prerogative, to:

- (1) Identify radiation safety problems;
- (2) Initiate, recommend, or provide corrective actions; and
- (3) Verify implementation of corrective actions.

(b) A licensee shall establish and state in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, and retain the current edition of these statements as a record until the Commission terminates the license.

§ 35.25 Supervision.

(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by § 35.11(b) of this part shall:

(1) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material and in the licensee's written quality management program;

(2) Require the supervised individual to follow the instructions of the supervising authorized user, follow the written radiation safety and quality management procedures established by the licensee, and comply with the regulations of this chapter and the license conditions with respect to the use of byproduct material; and

(3) Periodically review the supervised individual's use of byproduct material and the records kept to reflect this use.

(b) Licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

§ 35.27 Visiting authorized user.

(a) A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for sixty days each year if:

(1) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee;

(2) The licensee has a copy of a license issued by the Commission or an Agreement State, or a permit issued by a Commission or Agreement State broad licensee that is authorized to permit medical use, that identifies the visiting authorized user by name as an authorized user for medical use; and

(3) Only those procedures for which the visiting authorized user is specifically authorized by the license or permit are performed by that individual.

(b) A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in paragraph (a) of this section.

(c) A licensee shall retain the records specified in this section for three years after the visiting authorized user's last use of licensed material, but may discard the records if the visiting authorized user has been listed as an authorized user on the licensee's license.

§ 35.29 Administrative requirements that apply to the provision of mobile nuclear medicine service.

(a) The Commission will license mobile nuclear medicine service only in accordance with Subparts D, E and H of this part and § 31.11 of this chapter.

(b) Mobile nuclear medicine service licensees shall obtain a letter signed by the management of each client for which services are rendered that authorizes use of byproduct material at the client's address of use. The mobile nuclear medicine service licensee shall retain the letter for three years after the last provision of service.

(c) If a mobile nuclear medicine service provides services that the client is also authorized to provide, the client is responsible for assuring that services are conducted in accordance with the regulations in this chapter while the mobile nuclear medicine service is under the client's direction.

(d) A mobile nuclear medicine service may not order byproduct material to be delivered directly from the manufacturer or distributor to the client's address of use.

§ 35.31 Radiation safety program changes.

(a) A licensee may make minor changes in radiation safety procedures that are not potentially important to safety, i.e., ministerial changes, that were described in the application for license, renewal, or amendment except for those changes in §§ 35.13 and 35.606 of this part. Examples of such ministerial changes include: editing of procedures for clarity or conformance with local drafting policy or updating names, telephone numbers, and addresses; adoption of model radiation safety procedures published in NRC Regulatory Guides; replacement of equipment; reassignment of tasks among employees; or assignment of service contracts for services such as personnel dosimetry, radiation safety equipment repair or calibration, waste disposal, and safety surveys. A licensee is responsible for assuring that any change made is in compliance with the requirements of the regulations and the license.

(b) A licensee shall retain a record of each change until the license has been renewed or terminated. The record must include the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.

§ 35.32 Quality management program.

(a) Each applicant or licensee under this part, as applicable, shall establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following specific objectives:

(1) That, prior to administration, a written directive¹ is prepared for:

- (i) Any teletherapy radiation dose;
- (ii) Any gamma stereotactic radiosurgery radiation dose;
- (iii) Any brachytherapy radiation dose;
- (iv) Any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131; or
- (v) Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131;

(2) That, prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive;

(3) That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

(4) That each administration is in accordance with the written directive; and

(5) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

(b) The licensee shall:

- (1) Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of:
 - (i) A representative sample of patient administrations,
 - (ii) All recordable events, and
 - (iii) All misadministrations

to verify compliance with all aspects of the quality management program; these reviews shall be conducted at intervals no greater than 12 months;

(2) Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of paragraph (a) of this section; and

(3) Retain records of each review, including the evaluations and findings of

¹ If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

the review, in an auditable form for three years.

(c) The licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:

(1) Assembling the relevant facts including the cause;

(2) Identifying what, if any, corrective action is required to prevent recurrence; and

(3) Retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.

(d) The licensee shall retain:

- (1) Each written directive; and
- (2) A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in paragraph (a)(1) above, in an auditable form, for three years after the date of administration.

(e) The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The licensee shall furnish the modification to the appropriate NRC Regional Office within 30 days after the modification has been made.

(f)(1) Each applicant for a new license, as applicable, shall submit to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 a quality management program as part of the application for a license and implement the program upon issuance of the license by the NRC.

(2) Each existing licensee, as applicable, shall submit to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 by January 27, 1992 a written certification that the quality management program has been implemented along with a copy of the program.

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configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(c) A licensee shall also perform appropriate checks and tests required by this section following adjustment or repair of the dose calibrator.

(d) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(e) A licensee shall retain a record of each check and test required by this section for three years unless directed otherwise. The records required in paragraphs (b)(1) through (b)(4) of this section must include:

(1) For paragraph (b)(1), the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured, and the initials of the individual who performed the check;

(2) For paragraph (b)(2), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the signature of the Radiation Safety Officer;

(3) For paragraph (b)(3), the model and serial number of the dose calibrator, calculated activities, the measured activities, the date of the test, and the signature of the Radiation Safety Officer; and

(4) For paragraph (b)(4), the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the signature of the Radiation Safety Officer.

§ 35.51 Calibration and check of survey instruments.

(a) A licensee shall calibrate the survey instruments used to show compliance with this part before first use, annually, and following repair. The licensee shall:

(1) Calibrate all scales with readings up to 1000 millirem per hour with a radiation source;

(2) Calibrate two separated readings on each scale that must be calibrated; and

(3) Conspicuously note on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(b) When calibrating a survey instrument, the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated

exposure rate by not more than 20 percent, and shall conspicuously attach a correction chart or graph to the instrument.

(c) A licensee shall check each survey instrument for proper operation with the dedicated check source each day of use. A licensee is not required to keep records of these checks.

(d) A licensee shall retain a record of each survey instrument calibration for three years. The record must include:

(1) A description of the calibration procedure; and

(2) The date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the signature of the individual who performed the calibration.

§ 35.53 Measurement of radiopharmaceutical dosages.

A licensee shall:

(a) Measure the activity of each radiopharmaceutical dosage that contains more than 10 microcuries of a photon-emitting radionuclide before medical use;

(b) Measure the activity of each radiopharmaceutical dosage with a desired activity of 10 microcuries or less of a photon-emitting radionuclide before medical use to verify that the dosage does not exceed 10 microcuries;

(c) Retain a record of the measurements required by this section for three years. To satisfy this requirement, the record must contain the:

(1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

(2) Patient's name, and identification number if one has been assigned;

(3) Prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 10 microcuries;

(4) Date and time of the measurement; and

(5) Initials of the individual who made the record.

§ 35.57 Authorization for calibration and reference sources.

Any person authorized by § 35.11 of this Part for medical use of byproduct material may receive, possess, and use the following byproduct material for check, calibration, and reference use:

(a) Sealed sources manufactured and distributed by a person licensed pursuant to § 32.74 of this chapter or equivalent Agreement State regulations and that do not exceed 15 millicuries each;

(b) Any byproduct material listed in §§ 35.100 or 35.200 with a half-life not longer than 100 days in individual amounts not to exceed 15 millicuries;

(c) Any byproduct material listed in §§ 35.100 or 35.200 with a half-life longer than 100 days in individual amounts not to exceed 200 microcuries each; and

(d) Technetium-99m in individual amounts not to exceed 50 millicuries.

§ 35.59 Requirements for possession of sealed sources and brachytherapy sources.

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer, and shall maintain the instructions for the duration of source use in a legible form convenient to users.

(b) A licensee in possession of a sealed source shall:

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(2) Test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State and described in the label or brochure that accompanies the source.

(c) To satisfy the leak test requirements of this section, the licensee must:

(1) Take a wipe sample from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which radioactive contamination might be expected to accumulate or wash the source in a small volume of detergent solution and treat the entire volume as the sample;

(2) Take teletherapy and other device source test samples when the source is in the "off" position; and

(3) Measure the sample so that the leakage test can detect the presence of 0.005 microcuries of radioactive material on the sample.

(d) A licensee shall retain leakage test records for five years. The records must contain 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 microcuries, a description of the method used to measure each test sample, the date of the test, and the signature of the Radiation Safety Officer.

(e) If the leakage test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall:

(1) Immediately withdraw the sealed source from use and store it in accordance with the requirements in Parts 20 and 30 of this chapter; and

(2) File a report within five days of the leakage test with the appropriate NRC Office listed in § 30.6 of this chapter, with a copy to Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, describing the equipment involved, the test results, and the action taken.

(f) A licensee need not perform a leakage test on the following sources:

(1) Sources containing only byproduct material with a half-life of less than 30 days;

(2) Sources containing only byproduct material as a gas;

(3) Sources containing 100 microcuries or less of beta or gamma-emitting material or 10 microcuries or less of alpha-emitting material;

(4) 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; and

(5) Seeds of iridium-192 encased in nylon ribbon.

(g) A licensee in possession of a sealed source or brachytherapy source shall conduct a quarterly physical inventory of all such sources in its possession. The licensee shall retain each inventory record for five years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the signature of the Radiation Safety Officer.

(h) A licensee in possession of a sealed source or brachytherapy source shall measure the ambient dose rates quarterly in all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

(i) A licensee shall retain a record of each survey required in paragraph (h) of this section for three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area expressed in millirem per hour, the survey instrument used, and the signature of the Radiation Safety Officer.

§ 35.60 Syringe shields and labels.

(a) A licensee shall keep syringes that contain byproduct material to be administered in a radiation shield.

(b) To identify its contents, a licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical. The label must show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's name.

(c) A licensee shall require each individual who prepares a radiopharmaceutical kit to use a syringe radiation shield when preparing the kit and shall require each individual to use a syringe radiation shield when administering a radiopharmaceutical by injection unless the use of the shield is contraindicated for that patient.

§ 35.61 Vial shields and labels.

(a) A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

(b) To identify its contents, a licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical. The label must show the radiopharmaceutical name or its abbreviation.

§ 35.70 Surveys for contamination and ambient radiation exposure rate.

(a) A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

(b) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

(c) A licensee shall conduct the surveys required by paragraphs (a) and (b) of this section so as to be able to detect dose rates as low as 0.1 millirem per hour.

(d) A licensee shall establish radiation dose rate trigger levels for the surveys required by paragraphs (a) and (b) of this section. A licensee shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds a trigger level.

(e) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

(f) A licensee shall conduct the surveys required by paragraph (e) of this section so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute.

(g) A licensee shall establish removable contamination trigger levels for the surveys required by paragraph (e) of this section. A licensee shall

require the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds the trigger level.

(h) A licensee shall retain a record of each survey for three years. The record must include the date of the survey, a plan of each area surveyed, the trigger level established for each area, the detected dose rate at several points in each area expressed in millirem per hour or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters, the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

§ 35.75 Release of patients containing radiopharmaceuticals or permanent implants.

(a) A licensee may not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either:

(1) The measured dose rate from the patient is less than 5 millirems per hour at a distance of one meter; or

(2) The activity in the patient is less than 30 millicuries.

(b) A licensee may not authorize release from confinement for medical care of any patient administered a permanent implant until the measured dose rate from the patient is less than 5 millirems per hour at a distance of one meter.

§ 35.80 Technical requirements that apply to the provision of mobile nuclear medicine service.

A licensee providing mobile nuclear medicine service shall:

(a) Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

(b) Bring into each address of use all byproduct material to be used and, before leaving, remove all unused byproduct material and all associated waste;

(c) Secure or keep under constant surveillance and immediate control all byproduct material when in transit or at an address of use;

(d) Check survey instruments and dose calibrators as described in §§ 35.50 and 35.51, and check all other transported equipment for proper function before medical use at each address of use;

(e) Carry a radiation detection survey meter in each vehicle that is being used to transport byproduct material, and, before leaving a client address of use, survey all radiopharmaceutical areas of

51 FR 36932 use with a radiation detection survey meter to ensure that all radiopharmaceuticals and all associated waste have been removed:

51 FR 19240 (f) Retain a record of each survey required in paragraph (e) of this section for three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who performed the survey.

51 FR 3692 § 35.90 Storage of volatiles and gases. A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container. A licensee shall store a multi-dose container in a fume hood after drawing the first dosage from it.

58 FR 67657 § 35.92 Decay-in-storage. (a) A licensee may hold byproduct material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of § 20.2001 of this chapter if it:

- (1) Holds byproduct material for decay a minimum of ten half-lives;
- (2) Monitors byproduct material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey meter set on its most sensitive scale and with no interposed shielding;
- (3) Removes or obliterates all radiation labels; and
- (4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that it has decayed to background radiation level before disposal.

51 FR 19240 (b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section for three years. The record must include the date of the 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.

Subpart D—Uptake, Dilution, and Excretion

51 FR 36932 § 35.100 Use of radiopharmaceuticals for uptake, dilution and excretion studies.

A licensee may use any byproduct material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution, or excretion for which the Food and Drug Administration (FDA) has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).

51 FR 19240 § 35.120 Possession of survey instrument. A licensee authorized to use byproduct material for uptake, dilution, and excretion studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour.

Subpart E—Imaging and Localization

51 FR 36932 § 35.200 Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.

(a) A licensee may use any byproduct material in a diagnostic radiopharmaceutical or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing byproduct material for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).

(b) A licensee shall elute generators and prepare reagent kits in accordance with the manufacturer's instructions.

58 FR 39130 (c)(1) From August 23, 1990, to December 31, 1994, a licensee may depart from the manufacturer's instructions for eluting generators and preparing reagent kits for which the Food and Drug Administration (FDA) has approved a "New Drug Application" (NDA), by following the directions of an authorized user physician.

57 FR 45566 (2) Nothing in this section relieves the licensee from complying with other applicable NRC, FDA, and other Federal or State regulations.

51 FR 36932 § 35.204 Permissible molybdenum-99 concentration.

(a) A licensee may not administer to humans a radiopharmaceutical containing more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m.

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate or extract.

51 FR 19240 (c) A licensee that must measure molybdenum concentration shall retain a record of each measurement for three years. The record must include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in millicuries, the measured activity of the molybdenum expressed in microcuries, the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium, the time and date of the measurement, and the initials of the individual who made the measurement.

58 FR 67657 § 35.205 Control of aerosols and gases.

(a) A licensee that administers radioactive aerosols or gases shall do so in a room with a system that will keep airborne concentrations within the limits prescribed by § 20.1301 of this chapter. The system must either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

53 FR 27665 (b) A licensee shall administer radioactive gases only in rooms that are at negative pressure compared to surrounding rooms.

58 FR 67657 (c) Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a spill to reduce the concentration in the room to the occupational limit listed in § 20.1301 of this chapter. The calculation must be based on the highest activity of gas handled in a single container, the air volume of the room, and the measured available air exhaust rate.

53 FR 27665

(d) A licensee shall make a record of the calculations required in paragraph (c) of this section that includes the assumptions, measurements, and calculations made and shall retain the record for the duration of use of the area. A licensee shall also post the calculated time and safety measures to be instituted in case of a spill at the area of use.

53 FR 27665

(e) A licensee shall check the operation of reusable collection systems each month, and measure the ventilation rates available in areas of radioactive gas use each six months.

§ 35.300

Possession of survey instruments.

51 FR 36932

A licensee authorized to use byproduct material for imaging and localization studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Subpart F—Radiopharmaceuticals for Therapy

§ 35.300

Use of radiopharmaceuticals for therapy.

55 FR 34513

(a) A licensee may use any byproduct material in a radiopharmaceutical and for a therapeutic use for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). The licensee shall comply with the package insert instructions regarding indications and method of administration.

58 FR 39130

(b)(1) From August 23, 1990, to December 31, 1994, a licensee may depart from the package insert instructions regarding indications or methods of administration for a radiopharmaceutical for which the Food and Drug Administration (FDA) has approved a "New Drug Application" (NDA), provided that the authorized user physician has prepared a written directive as required by § 35.32(a).

57 FR 45566

(2) Nothing in this section relieves the licensee from complying with other applicable NRC, FDA, and other Federal or State regulations.

51 FR 36932

§ 35.310 Safety instruction.

(a) A licensee shall provide radiation safety instruction for all personnel caring for the patient receiving radiopharmaceutical therapy and

hospitalized for compliance with § 35.75 of this chapter. To satisfy this requirement, the instruction must describe the licensee's procedures for:

- (1) Patient control;
- (2) Visitor control;
- (3) Contamination control;
- (4) Waste control; and
- (5) Notification of the Radiation Safety Officer in case of the patient's death or medical emergency.

(b) A licensee shall keep for three years a list of individuals receiving instruction required by paragraph (a) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

§ 35.315 Safety precautions.

(a) For each patient receiving radiopharmaceutical therapy, and hospitalized for compliance with § 35.75 of this chapter, a licensee shall:

- (1) Provide a private room with a private sanitary facility;
- (2) Post the patient's door with a "Radioactive Materials" sign and note on the door or in the patient's chart where and how long visitors may stay in the patient's room;
- (3) Authorize visits by individuals under age 18 only on a patient-by-patient basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

(4) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of Part 20 of this chapter, and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

(5) Either monitor material and items removed from the patient's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste.

(6) Provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient.

(7) Survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room must not be reassigned until

removable contamination is less than 200 disintegrations per minute per 100 square centimeters; and

(8) Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage, and retain for the period required by § 20.2106(a) of this chapter a record of each thyroid burden measurement, its date, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

(b) A licensee shall notify the Radiation Safety Officer immediately if the patient dies or has a medical emergency.

§ 35.320 Possession of survey instruments.

A licensee authorized to use byproduct material for radiopharmaceutical therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Subpart G—Sources for Brachytherapy

§ 35.400 Use of sources for brachytherapy.

A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:

- (a) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
- (b) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
- (c) Gold-198 as a sealed source in seeds for interstitial treatment of cancer;
- (d) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;
- (e) Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and
- (f) Iodine-125 as a sealed source in seeds for interstitial treatment of cancer.

(g) Palladium-103 as a sealed source in seeds for interstitial treatment of cancer.

§ 35.404 Release of patients treated with temporary implants.

(a) Immediately after removing the last temporary implant source from a patient, the licensee shall make a radiation survey of the patient with a radiation detection survey instrument to

confirm that all sources have been removed. The licensee may not release from confinement for medical care a patient treated by temporary implant until all sources have been removed.

(b) A licensee shall retain a record of patient surveys for three years. Each record must include the date of the survey, the name of the patient, the dose rate from the patient expressed as millirem per hour and measured at one meter from the patient, the survey instrument used, and the initials of the individual who made the survey.

§ 35.406 Brachytherapy sources inventory.

(a) Promptly after removing them from a patient, a licensee shall return brachytherapy sources to the storage area, and count the number returned to ensure that all sources taken from the storage area have been returned.

(b) A licensee shall make a record of brachytherapy source use which must include:

- (1) The names of the individuals permitted to handle the sources.
- (2) The number and activity of sources removed from storage, the patient's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage;

(3) The number and activity of sources returned to storage, the patient's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

(c) Immediately after implanting sources in a patient the licensee shall make a radiation survey of the patient and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

(d) A licensee shall retain the records required in paragraphs (b) and (c) of this section for three years.

§ 35.410 Safety instruction.

(a) The licensee shall provide radiation safety instruction to all personnel caring for the patient undergoing implant therapy. To satisfy this requirement, the instruction must describe:

- (1) Size and appearance of the brachytherapy sources;
- (2) Safe handling and shielding instructions in case of a dislodged source;
- (3) Procedures for patient control;
- (4) Procedures for visitor control; and

(5) Procedures for notification of the Radiation Safety Officer if the patient dies or has a medical emergency.

(b) A licensee shall retain for three years a record of individuals receiving instruction required by paragraph (a) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

§ 35.415 Safety precautions.

(a) For each patient receiving implant therapy, a licensee shall:

(1) Not quarter the patient in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirements of § 20.1301(a) of this chapter at a distance of one meter from the implant:

(2) Post the patient's door with a "Radioactive Materials" sign and note on the door or in the patient's chart where and how long visitors may stay in the patient's room:

(3) Authorize visits by individuals under age 18 only on a patient-by-patient basis with the approval of the authorized user after consultation with the Radiation Safety Officer; and

(4) Promptly after implanting the material, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of Part 20 of this chapter, and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

(5) Provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before releasing the patient if the patient was administered a permanent implant.

(b) A licensee shall notify the Radiation Safety Officer immediately if the patient dies or has a medical emergency.

§ 35.420 Possession of survey instrument.

A licensee authorized to use byproduct material for implant therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose

rates over the range 1 millirem per hour to 1000 millirem per hour.

Subpart H—Sealed Sources for Diagnosis

§ 35.500 Use of sealed sources for diagnosis.

A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:

- (a) Iodine-125, americium-241, or gadolinium-153 as a sealed source in a device for bone mineral analysis; and
- (b) Iodine-125 as a sealed source in a portable imaging device.

§ 35.520 Availability of survey instrument.

A licensee authorized to use byproduct material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour. The instrument must have been calibrated in accordance with § 35.51 of this part.

Subpart I—Teletherapy

§ 35.600 Use of a sealed source in a teletherapy unit.

The regulations and provisions of this subpart govern the use of teletherapy units for medical use that contain a sealed source of cobalt-60 or cesium-137.

§ 35.605 Maintenance and repair restrictions.

Only a person specifically licensed by the Commission or an Agreement State to perform teletherapy unit maintenance and repair shall:

(a) Install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source; or

(b) Maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

§ 35.606 License amendments.

In addition to the changes specified in § 35.13 of this part, a licensee shall apply for and must receive a license amendment before:

(a) Making any change in the treatment room shielding;

Making any change in the location of the teletherapy unit within the treatment room:

(c) Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

(d) Relocating the teletherapy unit; or

(e) Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

§ 35.610 Safety instruction.

(a) A licensee shall post instructions at the teletherapy unit console. To satisfy this requirement, these instructions must inform the operator of:

(1) The procedure to be followed to ensure that only the patient is in the treatment room before turning the primary beam of radiation on to begin a treatment or after a door interlock interruption;

(2) The procedure to be followed if: (i) The operator is unable to turn the primary beam of radiation off with controls outside the treatment room or any other abnormal operation occurs; and

(ii) The names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted if the teletherapy unit or console operates abnormally.

(b) A licensee shall provide instruction in the topics identified in paragraph (a) of this section to all individuals who operate a teletherapy unit.

(c) A licensee shall retain for three years a record of individuals receiving instruction required by paragraph (b) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

§ 35.615 Safety precautions.

(a) A licensee shall control access to the teletherapy room by a door at each entrance.

(b) A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that will:

(1) Prevent the operator from turning the primary beam of radiation on unless each treatment room entrance door is closed;

(2) Turn the primary beam of radiation off immediately when an entrance door is opened; and

(3) Prevent the primary beam of radiation from being turned on following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

(c) A licensee shall equip each entrance to the teletherapy room with a beam condition indicator light

(d) A licensee shall install in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status

(1) A radiation monitor must provide visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source, and must be observable by an individual entering the teletherapy room.

(2) A radiation monitor must be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

(3) A radiation monitor must be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients.

(4) A licensee shall maintain a record of the check required by paragraph (d)(3) of this section for three years. The record must include the date of the check, notation that the monitor indicates when its detector is and is not exposed, and the initials of the individual who performed the check.

(5) If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter must be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in paragraph (d)(4) of this section.

(6) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

(e) A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient from the teletherapy unit console during irradiation.

§ 35.620 Possession of survey instrument.

A licensee authorized to use byproduct material in a teletherapy unit shall have in its possession either a portable radiation detection survey instrument capable of detecting dose rate over the range 0.1 millirem per hour to 100 millirem per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1,000 millirem per hour.

§ 35.630 Dosimetry equipment.

(a) A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(1) The system must have been calibrated by the National Institute of Standards and Technology

or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous four years; eighteen to thirty months after that calibration, the system must have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past twenty-four months by the National Institute of Standards and Technology

or by a calibration laboratory accredited by the AAPM. The intercomparison meeting must be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM.

The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

(b) The licensee shall have available for use a dosimetry system for spot-check measurements. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (a) of this section. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in paragraph (a) of this section.

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record must include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of this section.

the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM.

§ 35.632 Full calibration measurements.

(a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

(1) Before the first medical use of the unit; and

(2) Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding one year.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of:

(1) The output within ± 3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer constancy and linearity over the range of use;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

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(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in *Physics in Medicine and Biology* Vol. 16, No. 3, 1971, pp. 379-396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in *Medical Physics* Vol. 10, No. 6, 1983, pp. 741-771, and Vol. 11, No. 2, 1984, p. 213. [Both of these references have been approved for incorporation by reference by the Director of the Federal Register. Copies of the documents are available for inspection at the NRC Library, 7920 Norfolk Avenue, Bethesda, Maryland 20814. Copies of the documents are also on file at the Office of the Federal Register, 1100 L Street NW, Room 8301, Washington, DC 20408. A notice of any change in the material will be published in the Federal Register.]

(e) A licensee shall correct mathematically the outputs determined in paragraph (b)(1) of this section for physical decay for intervals not exceeding one month for cobalt-60 or six months for cesium-137.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the licensee's teletherapy physicist.

(g) A licensee shall retain a record of each calibration for the duration of use of the teletherapy unit source. The record must include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, an assessment of timer linearity and constancy, the calculated on-off error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.

§ 35.634 Periodic spot-checks.

(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

(1) Timer constancy, and timer linearity over the range of use;

(2) On-off error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b) of this part; and

(6) The difference between the measurement made in paragraph (b)(5) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(b) A licensee shall perform measurements required by paragraph (a) of this section in accordance with procedures established by the teletherapy physicist. That individual need not actually perform the spot-check measurements.

(c) A licensee shall have the teletherapy physicist review the results of each spot-check within 15 days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each spot-check. The licensee shall keep a copy of each written notification for three years.

(d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month that assure proper operation of:

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(3) Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(e) A licensee shall arrange for prompt repair of any system identified in paragraph (d) of this section that is not operating properly, and shall not use the teletherapy unit following door interlock malfunction until the interlock system has been repaired.

(f) A licensee shall retain a record of each spot-check required by paragraphs (a) and (d) of this section for three years.

The record must include the date of the spot-check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, an assessment of timer linearity and constancy, the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the calculated on-off error, the determined accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot-check.

§ 35.636 Safety checks for teletherapy facilities.

(a) A licensee shall promptly check all systems listed in § 35.634(d) for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by § 35.606 (a)-(d).

(b) If the results of the checks required in paragraph (a) of this section indicate the malfunction of any system specified in § 35.634(d), the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(c) A licensee shall retain for three years a record of the facility checks following installation of a source. The record must include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, and doors, and the signature of the Radiation Safety Officer.

§ 35.641 Radiation surveys for teletherapy facilities.

(a) Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by § 35.606 (a)-(d), the licensee shall perform radiation surveys with a portable radiation measurement survey instrument calibrated in accordance with § 35.51 of this part to verify that:

(1) The maximum and average dose rates at one meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field do not exceed 10

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millirem per hour and 2 millirem per hour, respectively; and
(2) With the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:

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(i) Radiation dose quantities per unit time in restricted areas are not likely to cause personnel exposures in excess of the limits specified in § 20.1201 of this chapter; and
(ii) Radiation dose quantities per unit time in unrestricted areas do not exceed the limits specified in § 20.1301 of this chapter.

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(b) If the results of the surveys required in paragraph (a) of this section indicate any radiation dose quantity per unit time in excess of the respective limit specified in that paragraph, the licensee shall lock the control in the off position and not use the unit:

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(1) Except as may be necessary to repair, replace, or test the teletherapy unit shielding or the treatment room shielding; or

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(2) Until the licensee has received a specific exemption pursuant to § 20.1301 of this chapter.

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(c) A licensee shall retain a record of the radiation measurements made following installation of a source for the duration of the license. The record must include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the off position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirem per hour, the calculated maximum quantity of radiation over a period of one week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer.

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§ 35.643 Modification of teletherapy unit or room before beginning a treatment program.

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(a) If the survey required by § 35.641 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by § 20.1301 of this chapter,

before beginning the treatment program the licensee shall:

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(1) Either equip the unit with stops or add additional radiation shielding to ensure compliance with § 20.1301(c) of this chapter.

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(2) Perform the survey required by § 35.641 again; and
(3) Include in the report required by § 35.645 the results of the initial survey, a description of the modification made to comply with paragraph (a)(1) of this section, and the results of the second survey.

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(b) As an alternative to the requirements set out in paragraph (a) of this section, a licensee may request a license amendment under § 20.1301(c) of this chapter that authorizes radiation levels in unrestricted areas greater than those permitted by § 20.1301(a) of this chapter. A licensee may not begin the treatment program until the license amendment has been issued.

§ 35.645 Reports of teletherapy surveys, checks, tests, and measurements.

A licensee shall mail a copy of the records required in §§ 35.636, 35.641, 35.643, and the output from the teletherapy source expressed as roentgens or rads per hour at one meter from the source and determined during the full calibration required in § 35.632, to the appropriate Commission Regional Office listed in § 30.6 of this chapter within thirty days following completion of the action that initiated the record requirement.

§ 35.647 Five-year inspection.

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(a) A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(c) A licensee shall keep a record of the inspection and servicing for the duration of the license. The record must contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

Subpart J—Training and Experience Requirements

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§ 35.900 Radiation Safety Officer.
Except as provided in § 35.901, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.32 to be an individual who:
(a) Is certified by:
(1) American Board of Health Physics in Comprehensive Health Physics;
(2) American Board of Radiology;
(3) American Board of Nuclear Medicine;
(4) American Board of Science in Nuclear Medicine; or
(5) Board of Pharmaceutical Specialties in Nuclear Pharmacy; or
(b) Has had classroom and laboratory training and experience as follows:
(1) 200 hours of classroom and laboratory training that includes:
(i) Radiation physics and instrumentation;
(ii) Radiation protection;
(iii) Mathematics pertaining to the use and measurement of radioactivity;
(iv) Radiation biology; and
(v) Radiopharmaceutical chemistry; and
(2) One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes the medical use of byproduct material; or
(c) Be an authorized user identified on the licensee's license.

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§ 35.901 Training for experienced Radiation Safety Officer.

An individual identified as a Radiation Safety Officer on a Commission or Agreement State license before October 1, 1986 need not comply with the training requirements of § 35.900.

§ 35.910 Training for uptake, dilution, and excretion studies.

Except as provided in §§ 35.970 and 35.971, the licensee shall require the authorized user of a radiopharmaceutical in § 35.100(a) to be a physician who:

(a) Is certified in:
(1) Nuclear medicine by the American Board of Nuclear Medicine;
(2) Diagnostic radiology by the American Board of Radiology; or
(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows:

(1) 40 hours of classroom and laboratory training that includes:
(i) Radiation physics and instrumentation;
(ii) Radiation protection;
(iii) Mathematics pertaining to the use and measurement of radioactivity;
(iv) Radiation biology; and
(v) Radiopharmaceutical chemistry; and

(2) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes:

- (i) Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
- (ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
- (iii) Administering dosages to patients and using syringe radiation shields;
- (iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and
- (v) Patient followup; or

(c) Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§ 35.920 Training for imaging and localization studies.

Except as provided in § 35.970 or 35.971, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in § 35.200(a) to be a physician who:

(a) Is certified in:

- (1) Nuclear medicine by the American Board of Nuclear Medicine;
- (2) Diagnostic radiology by the American Board of Radiology; or
- (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows:

(1) 200 hours of classroom and laboratory training that includes:

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity;
- (iv) Radiopharmaceutical chemistry; and

(v) Radiation biology; and

(2) 500 hours of supervised work experience under the supervision of an authorized user that includes:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Calibrating dose calibrators and diagnostic instruments and performing

checks for proper operation of survey meters:

(iii) Calculating and safely preparing patient dosages;

(iv) Using administrative controls to prevent the misadministration of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

(3) 500 hours of supervised clinical experience under the supervision of an authorized user that includes:

(i) Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) Administering dosages to patients and using syringe radiation shields;

(iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(v) Patient followup; or

(c) Has successfully completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§ 35.930 Training for therapeutic use of radiopharmaceuticals.

Except as provided in § 35.970, the licensee shall require the authorized user of radiopharmaceuticals in § 35.300 to be a physician who:

(a) Is certified by:

(1) The American Board of Nuclear Medicine; or

(2) The American Board of Radiology in radiology or therapeutic radiology; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows:

(1) 80 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(2) Supervised clinical experience under the supervision of an authorized user at a medical institution that includes:

(i) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals; and

(ii) Use of iodine-131 for treatment of thyroid carcinoma in 3 individuals.

§ 35.932 Training for treatment of hyperthyroidism.

Except as provided in § 35.970, the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows:

(a) 80 hours of classroom and laboratory training that includes:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in 10 individuals.

§ 35.934 Training for treatment of thyroid carcinoma.

Except as provided in § 35.970, the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows:

(a) 80 hours of classroom and laboratory training that includes:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in 3 individuals.

§ 35.940 Training for use of brachytherapy sources.

Except as provided in § 35.970, the licensee shall require the authorized

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user of a brachytherapy source listed in § 35.400 for therapy to be a physician who:

- (a) Is certified in:
- (1) Radiology or therapeutic radiology by the American Board of Radiology;
 - (2) Radiation oncology by the American Osteopathic Board of Radiology;
 - (3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
 - (4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or
- (b) Is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows:
- (1) 200 hours of classroom and laboratory training that includes:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity; and
 - (iv) Radiation biology;
 - (2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:
 - (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (ii) Checking survey meters for proper operation;
 - (iii) Preparing, implanting, and removing sealed sources;
 - (iv) Maintaining running inventories of material on hand;
 - (v) Using administrative controls to prevent the misadministration of byproduct material; and
 - (vi) Using emergency procedures to control byproduct material; and
 - (3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:
 - (i) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

- (ii) Selecting the proper brachytherapy sources and dose and method of administration;
- (iii) Calculating the dose; and
- (iv) Post-administration followup and review of case histories in collaboration with the authorized user.

§ 35.941 Training for ophthalmic use of strontium-90.

Except as provided in § 35.970, the licensee shall require the authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows:

- (a) 24 hours of classroom and laboratory training that includes:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity; and
 - (4) Radiation biology;
- (b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals that includes:
 - (1) Examination of each individual to be treated;
 - (2) Calculation of the dose to be administered;
 - (3) Administration of the dose; and
 - (4) Followup and review of each individual's case history.

§ 35.950 Training for use of sealed sources for diagnosis.

Except as provided in § 35.970, the licensee shall require the authorized user of a sealed source in a device listed in § 35.500 to be a physician, dentist, or podiatrist who:

- (a) Is certified in:
- (1) Radiology, diagnostic radiology, or therapeutic radiology by the American Board of Radiology;
 - (2) Nuclear medicine by the American Board of Nuclear Medicine; or
 - (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
- (b) Has had 8 hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes:

- (1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;
- (2) Radiation biology;
- (3) Radiation protection; and
- (4) Training in the use of the device for the uses requested.

§ 35.960 Training for teletherapy.

Except as provided in § 35.970, the licensee shall require the authorized user of a sealed source listed in § 35.600 in a teletherapy unit to be a physician who:

- (a) Is certified in:
- (1) Radiology or therapeutic radiology by the American Board of Radiology;
 - (2) Radiation oncology by the American Osteopathic Board of Radiology;
 - (3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
 - (4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or
- (b) Is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, supervised work experience, and supervised clinical experience as follows:
- (1) 200 hours of classroom and laboratory training that includes:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity; and
 - (iv) Radiation biology;
 - (2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:
 - (i) Review of the full calibration measurements and periodic spot checks;
 - (ii) Preparing treatment plans and calculating treatment times;
 - (iii) Using administrative controls to prevent misadministrations;
 - (iv) Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and
 - (v) Checking and using survey meters; and
 - (3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology

under the supervision of an authorized user at a medical institution that includes:

- (i) Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;
- (ii) Selecting the proper dose and how it is to be administered;
- (iii) Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and
- (iv) Post-administration followup and review of case histories.

§ 35.961 Training for teletherapy physicist.

The licensee shall require the teletherapy physicist to be an individual who:

(a) Is certified by the American Board of Radiology in:

- (1) Therapeutic radiological physics;
- (2) Roentgen ray and gamma ray physics;

(3) X-ray and radium physics; or

(4) Radiological physics; or

(b) Holds a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and has completed one year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a teletherapy physicist at a medical institution that includes the tasks listed in §§ 35.59, 35.632, 35.634, and 35.641 of this part.

§ 35.970 Training for experienced authorized users.

Physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of byproduct material on a Commission or Agreement State license issued before April 1, 1987 who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of Subpart J.

§ 35.971 Physician training in a three month program.

A physician who, before July 1, 1984, began a three month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program need not comply with the requirements of §§ 35.910 or 35.920.

§ 35.972 Recency of training.

The training and experience specified in this subpart must have been obtained

within the five years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

Subpart K—Enforcement

35.990 Violations.

➤ (a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of—

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

§ 35.991 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in Part 35 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 35 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 35.1, 35.2, 35.8, 35.12, 35.18, 35.19, 35.57, 35.100, 35.600, 35.901, 35.970, 35.971, 35.990, 35.991, and 35.999.

§ 35.999 Resolution of conflicting requirements during transition period.

If the rules in this part conflict with the licensee's radiation safety program as identified in its license, and if that license was approved by the Commission before April 1, 1987 and has not been renewed since April 1, 1987, then the requirements in the license will apply. However, if that licensee exercises its privilege to make minor changes in its radiation safety procedures that are not potentially important to safety under § 35.31 of this chapter, the portion changed must comply with the requirements of this Part. At the time of license renewal and thereafter, these amendments to this Part shall apply.

Instructions For Use Of A Geiger Counter

1. Perform A Battery Check.

- a. Turn on the Geiger Counter by moving the center toggle switch to the first position noted as "BATT". The indicator needle should move to the portion of the dial which indicates "BATT OK".
- b. Replace the batteries (two "D" cells), if the needle does not travel to this area.

2. Perform A Calibration Check.

- a. Look on the side or bottom of the meter case to find the "calibration record" label. This label will specify a "Source Check" dose rate in millirad per hour (mR/hr).
- b. Move the center toggle switch to select the proper multiplication factor so the check source dose rate will measure the dose rate specified by the "Source Check".
- c. Hold the detector probe in contact with the check source for approximately 30 seconds and read the result. The probe should be orientated to match the probe outline which surrounds the check source. The result should agree closely with the "Source Check" dose rate.
- d. Notify the RSO if the measured dose rate does not agree with the "Source Check" dose rate.

3. Survey Technique

- a. Turn on the survey meter and locate an area where only background levels of radiation are present. The background dose rate should be less than 0.05 mR/hr.
- b. Survey all areas where displaced seeds may be located. Be sure to carefully survey all trash containers, bed linens and foley sets before they are released.
- c. If a source is discovered, slowly survey in one direction to locate the area of highest exposure. Return to the point of highest exposure and survey along a 90 degree axis from the first survey axis. Identify the highest exposure point. The seed should be located directly below this point.
- d. Use forceps to pick up the displaced seed (approx. 5 mm in length and 1 mm diameter) and place into the lead shield designated for seed recovery.
- e. Return displaced seeds to the Nuclear Medicine Hot lab. Notify security for after hours assistance.

William W. Backus Hospital
Nuclear Medicine Department

Iodine-125 Seed Package Survey Procedures

1. Wear ring badge and protective gloves before beginning the package survey procedure.
2. Visually inspect the package for damage and survey with a GM meter. Record results on the Nuc. Med. radionuclide receipt form. Note: GM surveys of I-125 packages should always be at background levels.
3. Wipe test outer surface of the package.
4. Open package and verify the calibration certification paperwork with the vial shield information. The certification number, lot number, total activity and calibration date should be cross verified.
5. Save the certification and the yellow packing list forms.
6. Open the lead shield and remove plastic wrap from the source vial.
7. Carefully remove the vial cap, insert a Q-tip into the vial and wipe the inner surface of the glass vial. Close the vial and return to the shield.
8. Count the package and vial wipe tests.
9. Set the spectroscaler to window "in", threshold "20 keV" and window "200".
10. Count a blank tube and the Iodine-129 (Simulated I-125) standard and record the results.
11. Count the package and vial wipes and record the results. Calculate the net counts for each sample by subtracting the blank result from the standard, package and vial counts.
12. Determine the calibration factor by dividing the standard dpm (Sim. I-125 Standard - 18,204 dpm) by the standard cpm to derive the dpm/cpm factor.
13. If either the package or vial results are greater than 200 dpm, notify Mike Bohan at Yale-New Haven Hospital, Radiation Safety Office. (785-2950, 340-3255 Digital Beeper)
14. GM Survey the shipping box. If the packaging is indistinguishable from background radiation levels, deface all radioactive labeling and discard as normal trash.
15. Retain top copy of the certification and the packing list for Nuc. Med. records. Give the dosimetrist the carbon copies of the certification when they remove sources for implant.



The William W. Backus Hospital

Michael T. Moore, President and Chief Executive Officer

326 Washington Street, Norwich, Connecticut 06360
Phone (203) 889-8331

TO: LEE RUMMEL

FROM: JEFFREY C. RUDIKOFF, M.D., R.S.O.

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

DATE: MARCH 2, 1994

The security guard on duty shall accept delivery of packages containing radioactive material that arrive during other than normal working hours. Packages should be placed on a cart or wheelchair and taken immediately to the Nuclear Medicine Department Hot Lab. 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, Jeffrey C. Rudikoff, M.D., at Extension 2233.

	Name	Home Telephone
Radiation Safety Officer	Jeffrey C. Rudikoff, M.D.	[Redacted] ext 6
D.I. Department Manager	Ted Lombardo	
Chief Nuc. Med. Tech.	Joyce Marcinek	

JCR:mck

cc: T. Lombardo ✓
J. Marcinek ✓
F. Andrusiewicz

THE WILLIAM W. BACKUS HOSPITAL
I-125/Pd-103 PROSTATE BRACHYTHERAPY TRAINING PROGRAM

Purpose: To provide training to the Nuclear Medicine Technologists, Dosimetrist, Referring Physician, and the Radiation Safety Officer commensurate with their involvement in the I-125/Pd-103 Prostate Brachytherapy Program at Backus Hospital.

Frequency: Initially, before first involvement in the Prostate Brachytherapy Program and with annual refresher training.

Training Summary

1. Program Requirements
 - a. NRC Regulations and License commitments
 - 10 CFR 19
 - 10 CFR 20
 - 10 CFR 35
 - Reg. Guide 10.8
 - NRC License
 - b. Quality Management Program
 - Review QMP Program
 - c. Prostate Implant Program Requirements
 - Review Brachytherapy Policy and Procedure Manual

2. Source Ordering and Receipt Procedures
 - a. Patient Selection and Referral for Prostate Implant
 - b. Volume Study
 - c. Pre-planning process
 - Typical Source Activity Ranges for I-125 and Pd-103 Implants
 - d. Authorized User Written Directive
 - Signed and Dated Before Ordering
 - e. Source Ordering Procedures
 - Order Confirmation by FAX to and from Manufacturer
 - Order and Confirmation Checked Against Written Directive
 - Source Activity Within Expected Range
 - I-125 (0.3 - 0.6 mCi)
 - Pd-103 (0.6 - 1.5 mCi)

- f. Source Receipt Procedures
 - Package Survey
 - Opening Package
 - Verifying Source Number and Activity with Written Directive
 - Completion of Source Log Record
 - Storage of Package Until Implant Date

- g. Quality Checks in Nuclear Medicine Before Implant
 - Dosimetrist
 - Count seeds
 - Dose Calibration Check of at least 4% of Seeds
 - Seed Activity Within 10% of Calibration Certification
 - Verify Written Directive with Calibration Certification
 - Double Check Seed Leak Test
 - Prepare sources for transport to Operating Room
 - Complete Inventory Log Before Transport

 - NMed Tech
 - Seed Leak Test
 - Double Check Seed Count
 - Double Check Seed Calibration
 - Double Check Inventory Log

 - Discrepancy Reporting Requirements
 - Radiation Safety Officer
 - Authorized User

- h. Return of Unused Sources After Implant
 - Completion of Inventory Log After Implant
 - Storage for Decay Program
 - > 10 Half lives and Geiger Mueller Survey Requirements Before Release
 - Quarterly Inventory Requirements

3. Post Implant Procedures

- a. Return of Patient Excreted Seeds from Nursing Floors or From Patient
 - Verify seed number and update Inventory log
 - Examine seed to ensure it is undamaged
 - Return seed to original vial whenever possible

- b. Procedures for Ruptured Seeds
 - Isolate leaking source in sealed container
 - Survey and wipe test suspect areas
 - Notify Radiation Safety Officer of Contamination Events
 - Decontamination Procedures

**THE WILLIAM W. BACKUS HOSPITAL
I-125 BRACHYTHERAPY TRAINING PROGRAM**

Instructional Training: Operating Room Staff
PACU Staff
A-4 and CCU Staff
Nurse Anesthetists
Anesthesiologists
Security Personnel

Informative Training: IV and Respiratory Therapists
Admitting
CPD Staff
ESD Staff
Escort Volunteers

The instructional training will be performed by an attending surgeon on staff at W.W. Backus Hospital, Health Physicist, Yale New Haven hospital and Brachytherapy Safety Nurse Coordinator at the W.W. Backus Hospital.

The informative training will be given as a written handout by the W.W. Backus Hospital Brachytherapy Safety Nurse Coordinator or their designee. The staff member will be given along with the handout, a copy of the manual and informative article. They will be required to sign their name that they attended the inservice. They are also reminded to contact me or my designee if any questions should arise regarding the care of a Brachytherapy patient.

The history of prostate carcinoma and patient selection will be given by the W.W. Backus Hospital attending surgeon.

The physiology of radioisotopes, NRC regulations, safe handling of Iodine 125, radiation hazards, and demonstration of a Geiger counter will be given by the Health Physicist.

Nursing considerations, pre-operative and post-operative patient teaching, surgical suite preparation, and post-operative room preparation will be given by the W.W. Backus Hospital Brachytherapy Safety Nurse Coordinator.

The NRC requires yearly re-certification of all staff members involved with the program, therefore each January a re-certification program will be required. This would eliminate re-certification each month. This program must be made available for the convenience of the staff as it is mandatory.

For those staff not able to attend, a copy of the program will be on a video cassette and available to be viewed. The staff members will be required to take a post-test. The updated manual also must be reviewed by all staff members. Signature, date, and social security number are required.

The Brachytherapy Safety Nurse Coordinator will answer any written or oral questions. The list of authorized staff members are kept in the files of the conference room outside of the Operating Room.

INSERVICE MATERIAL FOR BRACHYTHERAPY:

Thank you for attending our Brachytherapy I-125 Seed implantation inservice program. All staff must be inserviced first before being allowed to participate in any portion of Brachytherapy procedure as well as care for patients post-operatively.

Prior to the seed implant procedure a prostate volume study is done in the SDS LMTU minor surgery rom by the surgeon.

One week prior to surgery: Labs, EKG, CXR, Bone Scan will be completed.

One day prior to surgery: The patient will be required to call SDS in order to ascertain a time to arrive to the hospital. He will have been instructed by the surgeon to be on a clear liquid diet, administer to himself a fleet enema, and be NPO after midnight.

Day of surgery: Upon arising he will administer to himself a fleet enema.

When he arrives to the SDS department the assigned SDS nurse will interview him as well as the Anesthesiologist. At the same time the OR is preparing for surgery.

The Medical Physicist or Dosimetrist will have gone to the Nuclear Medicine Department to remove the brachytherapy seed sources. See page 9: Subject: Releasing Isotopes for Use of brachytherapy Procedure Manual. The seed sources will then be transported to the operating room in a lead shielding pig.

The seeds are now prepared for sterilization. See page 11 of the brachytherapy policy and procedure manual, Section: Sterilization and Preparation of Seeds. It must be noted and recorded on the sterilization log the time, temperature and pressure the seeds at the completion of the sterilization cycle. The seed sources must never be exposed to temperatures greater than 272° and pressure greater than 35 PSI. Radioactive signs will hang on both doors of the OR prior to the seeds arriving to the operating room

The dosimetrist will have scrubbed, and after drying his hands will then place his decontaminated ring badge on, don his gown and gloves with the assistance of the surgical nurse so that he may load the sterile seeds into the appropriate Manan needles. The dosimetrist will count the seeds after sterilization to insure all seeds are accounted for. He will then proceed to load the seeds.

The dosimetrist loads the seeds at a sterile table, wearing a lead apron and thyroid shield. The acrylic lead shield must be placed on the table to shield the loaded needles. Bone wax is used to occlude the tips of the needles after they have been loaded. The loaded needles are then placed into the acrylic needle holder that the dosimetrist brings on the day of surgery. This holder is a model of the template used during the implant procedure.

Once the OR is ready, the patient will be transported to the OR and will be interviewed by the brachytherapy safety nurse coordinator or her designee using the pre op assessment form. She will identify the patient as follows: Asking his name and checking it to the wrist bracelet imprint as well as the chart, and a third check which consists of comparing the attached copy of his photo ID, ie drivers license. This document will be copied upon admission and should be attached to the pre-op assessment form in the SDS department. The remainder of the interview is done in the usual manner.

The patient is then brought into the OR. A spinal anesthetic is administered by the anesthesiologist. The patient is placed on the OR bed and onto the special GU wedge mattress which is kept in the GU room.

The patient is then positioned in the lithotomy position by the surgeon, making sure the B&K US machine and necessary equipment are ready for use.

The foley is inserted and bladder filled by the surgeon. He will then shave and prep the perineum and apply an Ioban drape to the perineum to isolate the scrotum and penis.

At the completion of the procedure, the Health physicist or dosimetrist will perform a complete room survey to insure that no seeds remain in the room, trash, linen, as well as survey the patient to monitor his radiation level. He will complete this information on the Seed accountability form.

The patient is then transferred to PACU unit. He will be recovered in the isolation room by a previously inserviced nurse. The unit will contain a urine container, linen hamper, trash hamper, lead pig, long handled forcep, urine strainer and GM Monitor. Radioactive sign must be posted on the door. All staff caring for the patient will wear their assigned TLD Badges. It is important to remember all items in the room must be surveyed with the GM monitor before they are able to leave the room. Before the patient is discharged to the A4 unit, the entire unit is surveyed along with the patient linens on the stretcher.

With the A4 room, restrictions must be posted: No pregnant women and no children under the age of 18 may visit without the consent of the Radiation Safety Officer. TYPE OF RADIOACTIVE SUBSTANCE AND ACTIVITY will be listed on the signs.

Remember to MAINTAIN TIME AND DISTANCE when caring for the patient. An ice bag should be placed at the perineum to reduce swelling and prevent the formation of a hematoma.

The IDEAL SITUATION IS TO HAVE THE patient's perineum facing away from the door.

Keep the foley bag at one side of the stretcher instead of the foot to keep you from undue exposure. Monitor the urine for color, quantity and a dislodged seed from the opposite side.

Two I-125 patients may be housed in the same room.

A urine collection container must remain in the room until it has been surveyed.

A urine strainer must be used when the foley is removed to monitor for any lost seeds. This is when the privacy screen should be used along with the urinal.

The patient will be restricted to the PACU isolation room and A4 private room until discharged home.

Bedlinen, trash, urine and entire room will be surveyed by a qualified user of a Geiger Counter before any item can be removed.

ONCE THE ROOM HAS BEEN SURVEYED, THE ROOM MAY BE CLEANED IN THE USUAL MANNER. The Seed Accountability Sheet must be kept with the patient's chart until discharge. Then it is distributed to
1. Med Rec. 2. Bracytherapy log book 3. Health Physicist

IN THE EVENT THAT A DISLODGED SEED IS FOUND: EX: BED LINEN THE FOLLOWING WILL APPLY:

NEVER TOUCH THE SEED WITH YOUR BARE HANDS
USING A LONG HANDLED UNSTERILE FORCEP
CAREFULLY PICK UP THE SEED(SO NOT TO CRUSH THE SEED)AND PLACE IT INTO THE LEAD PIG CONTAINER PROVIDED BY THE NUCLEAR MEDICINE DEPARTMENT. Call Joyce Marcinek at 4249 or Dr. Rudikoff for instructions on transporting the seed back to the department. These recovered seeds are held in storage for decay.

If a seed is recovered after 3:30 P.M., after placing the seed into the lead "PIG", notify Security and they will transport the PIG to the Nuclear Medicine Hot Lab. Make sure to label the Pig with the patient's name and unit #. The security person will leave a note to the day staff of Nuclear Medicine to alert them that a seed has been delivered.

ALL STAFF WORKING WITH BRACHYTHERAPY PATIENTS MUST BE INSERVICED FIRST.

ALL STAFF CARING FOR BRACHYTHERAPY PATIENTS MUST MONITOR THEIR RADIATION LEVELS BY WEARING FILM BADGES. IT IS NOT NECESSARY TO WEAR LEAD APRONS WHEN CARING FOR PATIENTS.

The following instructions will be given to the patient: WHEN DISCHARGED:

Do not drive for 24 hours

AVOID HEAVY LIFTING FOR 2 DAYS. AFTER THAT TIME YOU MAY RESUME LIGHT ACTIVITY.

Pink urine is normal for 24 hours however if deep cranberry colored urine or if clots are observed, call the Urologist.

Slight burning sensation and bleeding under the scrotum or blood-tinged urine is expected. This is caused by the needles. If pain or bleeding is noted, call the Urologist.

Pink tinged urine may continue for several days. Drinking large amounts of water or fluids help to flush this out of the bladder.

Avoid caffeine and alcoholic beverages which can cause bladder spasms and irritation.

After the foley is removed, he may feel a burning sensation or an urge to urinate. This is normal for a short period of time. If however after six hours he is unable to pass his urine, or if he is feeling a sense of fullness in the bladder area, call YOUR UROLOGIST.

We ask the patient to strain his urine for the first 24 hours after discharge with the disposable strainer provided.

RADIATION SAFETY TO PATIENT:

1. As a precaution, avoid close contact with pregnant women.
2. As a precaution, avoid holding a child for any length of time on your lap for 6 months.

3. EXPLAIN THAT THE PATIENT IS NOT radioactive AND THAT ANY ITEM HE MAY TOUCH DOES NOT BECOME SO. ALL BODY FLUIDS SUCH AS URINE, SPERM OR FECES ARE NOT RADIOACTIVE. ALTHOUGH THE AMOUNT OF RADIATION IS VERY SMALL, THESE SEEDS MUST BE TREATED WITH CARE. SOMETIMES SEEDS ARE INSERTED CLOSE TO THE BLADDER AND CAN TRAVEL INTO THE BLADDER. IT IS THAT REASON WHY WE RECOMMEND THAT YOU STRAIN YOUR URINE FOR THE NEXT TWO WEEKS.

IF A SEED IS FOUND, PICK IT UP WITH A disposable spoon, DO NOT PICK IT UP WITH YOUR HANDS. PLACE THE SEED INTO A PIECE OF TIN FOIL AND PLACE IT INTO A GLASS JAR WITH A LID. CALL 4249 NUCLEAR MEDICAL DEPARTMENT FOR INSTRUCTIONS .

4. Sex may be resumed after 2 weeks. A condom must be used for one month after the procedure, in the unlikely event of a seed coming out with the ejaculate. The patient may notice the ejaculate is dark brown or black for several weeks after the procedure. This is due to old blood from the procedure and is discarding off in the ejaculate. This is normal and will stop in a few weeks.

IT IS EXPLAINED THAT THE PATIENT MUST CONTINUE TO SEE HIS UROLOGIST AFTER THE SURGERY IS COMPLETE. A CAT SCAN MAY BE ORDERED TO DETERMINE THE POSITION OF THE SEEDS.

APPOINTMENTS WILL BE GIVEN TO THE PATIENT FOR CONTINUED FOLLOW-UP CARE. THE PATIENT WILL BE ENCOURAGED TO WRITE ANY QUESTIONS DOWN THAT HE HAS AND PRESENT THEM TO THE UROLOGIST.

8/19/94
A:SEMINAR1