

**PETERSBURG HOSPITAL COMPANY, LLC
d/b/a SOUTHSIDE REGIONAL MEDICAL CENTER
NUCLEAR MEDICINE DEPARTMENT
801 SOUTH ADAMS STREET
PETERSBURG, VA 23803**

MS 16

September 6, 2007

Q-8

Nuclear Regulatory Commission
Licensing Assistance Team
Attn. Shirley Xu
475 Allendale Road
King of Prussia, PA 19406-1415

Subject: 1. Request for continuing education in 35.300 Therapy.
2. Request for radiation safety procedure in 35.300 Therapy.
3. Request to add authorized users to NRC License #45-00317-02.

Dear Shirley Xu:

03003301

Thank you for the phone call regarding the additional information needed to process **Control Number 140928**, NRC Radioactive Materials License # 45-00317-02.

1. I have performed or assisted in the administration of 43 (35.300) therapies from 1/1/2000 – 8/30/2007 under the supervision of the RSO or authorized user. This figure is documented by the written directive and the quarterly and annual review signed by the Radiation Safety Officer.
Also, I have worked closely with Dr. Dean Broga over the past 11 years in performing ALARA and Programmatic Reviews, including quarterly quality assurance reviews which cover all areas of our license including therapies covered under 35.300.
2. I have included the following radiation safety procedures for 35.300 therapy:
 - I-131 Inpatient Therapy Administration
 - Radiation Safety during Inpatient I-131 Therapeutic Administration
 - Emergency Procedures for;
 - Minor Spills of Liquids and Solids
 - Major Spills of Liquids and Solids
3. I would like to add the following physician(s) to our license for 35.400 use.
 1. Olubunni Abayomi, M.D.
 2. Mitchell Anscher, M.D.
 3. Michael Hagan, M.D.

These physicians are currently authorized users for manual brachytherapy (10 CFR 35.400) at the Virginia Commonwealth University, Medical College of Virginia Campus.

140928

I have included:

1. Letter of attestation from Dean W. Broga, Ph.D.
2. RSC Authorized User matrix including above physicians.

If I can provide anymore information please contact me at (804) 862-5584 or kevin_mullen@chs.net

Sincerely,

A handwritten signature in black ink, appearing to read "Kevin Mullen". The signature is fluid and cursive, with the first name "Kevin" being more prominent than the last name "Mullen".

Kevin Mullen
Manager of Nuclear Medicine

SOUTHSIDE REGIONAL MEDICAL CENTER
NUCLEAR MEDICINE DEPARTMENT

Date: 11-21-2002

Number: 1805

Subject: I-131 Inpatient Therapy Administration

I. Indications

- A. Residual thyroid cancer after thyroidectomy that shows iodine uptake.
- B. Ablation of residual thyroid tissue after subtotal thyroidectomy for thyroid cancer.

II. Contraindications

- A. The patient must not be pregnant or breast-feeding.
- B. A patient with thyroid cancer must have had an I-131 whole body scan within the last 2 weeks.
- C. A patient undergoing ablation of residual thyroid tissue must have had an I-131 scan showing a thyroid remnant within the 2 weeks preceding therapy.
- D. The patient must not have stopped taking all antithyroid medications for at least 2 days.
- E. The patient must not have received any iodinated IV contrast material within the last 3-4 weeks, because this will affect the uptake of I-131.

III. Patient Preparation

- A. All premenopausal women 13-50 years old must have a serum pregnancy test performed within 80 hours and the test results available before the treatment. The only exception is if a patient has been sterilized surgically (hysterectomy or tubal ligation).

IV. Radiopharmaceutical

- A. I-131

V. Dose

- A. The authorized user (physician) will determine the desired activity to be administered to the patient.

VI. Procedure

- A. The technologist should complete the written directive. The authorized user (physician) treating the patient will verify the information listed on the written directive and sign it.
- B. The prescribing physician will discuss the treatment and the radiation precautions with the patient and will verify the dose calculations.
- C. The dose is then administered orally to the patient.

VII. Additional Notes

- A. Radiation Safety during Inpatient I-131 Therapy #225 and Bioassay #235.

Reviewed: 2-28-03, KM; 3-11-04, KM; 5-6-05, KM; 2-8-07, KM

Revised: 8-1-07, KM

SOUTHSIDE REGIONAL MEDICAL CENTER
NUCLEAR MEDICINE DEPARTMENT

Date: 01-14-2003

Number: 225

Subject: Radiation Safety during Inpatient I-131 Therapeutic Administration

Policy: The treatment dose is determined by the authorized user (physician) in consultation with the referring physician.

Procedure: I. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room with sanitary facilities and should be without carpet.

II. Prepare the room for the procedure as follows:

A. Cover, with leak-proof absorbent paper, large surfaces (the bed, chairs, and the floor around the toilet), and with plastic wrap, small items (telephone, door knobs, bed remote control, television control, and nurse call cord) that are likely to be contaminated.

B. Prepare separate containers for linen, disposable waste, and non-disposable contaminated items. Place a single large re-sealable plastic bag in each box, or supply several small plastic bags.

C. Determine whether urine will be collected or released into the sanitary sewage system. If urine is to be collected, prepare collection containers.

1. Containers should be unbreakable and closable.

2. If there is no need for assay or volumetric determination and urine will be decayed in storage, add to each container an absorbent such as vermiculite.

3. To avoid room contamination in the case of a spill, place containers in a box or deep tray that has been lined with a plastic bag and absorbent paper or vermiculite.

4. Supply a few half-value layers of shielding for each container.
(For I-131, one half-value layer is approximately 3 mm of lead.)

5. Supply a wide mouth anti-splash funnel if necessary.

D. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use as necessary by nursing and nuclear medicine personnel.

III. Order disposable table service for the duration of the patient's stay. Inform the Environmental Services Office that personnel should stay out of the room until otherwise notified.

IV. If applicable, supply the nurses with film badges, TLDs, or pocket ionization chambers (see Personnel Exposure).

V. Brief the nurses on radiation precautions. Use the form "Nursing Instructions for Patients Treated with I-131". Allow time for questions and answers during the briefing. Leave a written copy of the radiation safety precautions in the patient's chart or at the nurse's station.

VI. Brief the patient on radiation safety procedures for the administration, visitor control, urine collection, radioactive waste and other items as applicable.

VII. Only those persons needed for medical, safety or training purposes should be present during the administration.

VIII. Following administration of the dose, measure the exposure rate at the mouth, along the esophagus and the stomach to ensure that the dose reached the stomach and didn't adhere to the tissue of the mouth. Then measure the exposure rate in mR/hr at bedside, at 1 meter from bedside and in the surrounding hallway and rooms (limit in unrestricted areas is 2 mrem/hr). Record this and any other necessary information on the nursing instructions form and patient history form. **Post the room with a "Caution Radioactive Materials" sign.**

If the exposure rate in any of the surrounding areas approaches 2 mR/hr the following should be done:

A. The estimated exposure to personnel and patients in the area must be considered. The occupancy of the area and the expected duration of the therapy can be used to estimate the dose. Since the patient will excrete a significant amount of the radionuclide in the first 8 to 12 hours, this may be considered in the estimate. The following limits must be met:

1. The dose to any individual present in the area during a period of 1 year must be less than 100 rems.
2. The estimated dose to any individual over the 1 year period must include all sources of radiation exposure, such as x-ray exposure and other therapies.

B. If the estimated exposure to any individual exceeds this limit, the Radiation Safety Officer (RSO) must be notified immediately and corrective action taken.

C. A survey must be made early the next day to verify that any dose reduction due to excretion has been accurately accounted for. If the radiation level exceeds the estimated level, the RSO must be notified immediately and corrective action taken.

D. Records of all estimated doses, including the parameters used and the results of all surveys must be recorded on the patient history form.

IX. Measure exposure and mark a visitor's "safe line" on the floor with tape as far from the patient as possible (2 mrem/hr).

X. For patients treated with 30 mCi or more of I-131, within 3 days of the administration, measure the thyroid burden of all personnel who helped prepare or administer the dose. Also, if a substantial contamination problem is identified in the patient's room, consider a thyroid burden assay for patient care personnel within 3 days of the administration. Make a record of the worker's name, amount of I-131 activity in a thyroid phantom in microcuries and associated counts per minute, the counts per minute from the worker's thyroid, the calculated thyroid burden and date.

XI. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area.

XII. Do not release any patient until the exposure rate from the patient is less than 5 mR/hr at 1 meter. Measure this exposure rate with an ionization-type survey meter at a distance of 1 meter from the umbilicus while the patient is standing or, if the patient is not ambulatory, 1 meter from the bedside with the patient supine.

XIII. Before using the room for general occupancy, it must be decontaminated and released to the Admitting Office.

A. Remove all absorbent paper and place it in the appropriate container.

B. Transfer all containers to a decay-in-storage or decontamination area.

C. Use a low-range GM survey meter and swipes to check for room contamination. Clean contaminated areas until removable contamination is less than 200 dpm/100 cm². If the contamination is fixed, exposure rates will be less than 1mR/hr with the GM detector in contact with the contaminated surface. All swipes should be counted using a NaI detector.

D. If a significant contamination problem is found, either the nuclear medicine staff or environmental services, under the supervision of the nuclear medicine staff, will clean the room using isolation procedures. The room should then be re-surveyed.

E. Call the Environmental Services Office to remove the cleaning restriction and call the Admitting Office to return the room to the vacant list.

Reviewed: 2-17-04, KM; 2-16-05, KM; 5-6-06, KM; 3-14-07, KM; 8-1-07, KM

Revised:

**SOUTHSIDE REGIONAL MEDICAL CENTER
NUCLEAR MEDICINE DEPARTMENT**

Date: 01-14-2003

Number: 135

Subject: Emergency Procedure
Minor Spills of Liquids and Solids
Major Spills of Liquids and Solids

Purpose: To establish a set of guidelines on what actions to take in the event of an internal nuclear material release. Included is a list of people to contact in this event. A copy of the department plan and hospital wide Hazmat Internal plan are attached.

Emergency Call Roster

*waiting
to
Revise.*

Name	Position	Ext.	Pager#	Home#
Jo Anne Walker, MD	Radiation Safety Officer	5850	351-3522	[REDACTED]
Kevin Mullen	Nuclear Medicine Manager	5584		[REDACTED]
Cary Straton, MD	Medical Director, Radiology	5041	256-3948	[REDACTED]
Kevin Sale	Radiology Director	5048	717-8592	[REDACTED]
On Call Tech.	Nuclear Medicine Tech		717-8552	
Thomas Nichols	Nuclear Medicine Tech	5584		[REDACTED]
Michelle Clapp	Nuclear Medicine Tech	5584		[REDACTED]
Sherry Smith	Registered Nurse	5584		[REDACTED]

Reviewed: 8-10-04, KM; 3-13-07, KM

Revised: 9-04-03, KM; 2-17-04, KM; 2-16-05, KM; 3-26-06, KM; 4-2-07, KM

**PERSONAL INFORMATION WAS REMOVED
BY NRC. NO COPY OF THIS INFORMATION
WAS RETAINED BY THE NRC.**



Emergency Procedures



Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent paper.
3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a GM survey meter. Check the area around the spill. Also check your hands, clothing, and shoes for contamination.
5. Report the incident to the Radiation Safety Officer.
6. The Chief Technologist will supervise the cleanup of the spill and will complete a Radioactive Spill Report and a final survey of the area.

Major Spills of Liquids and Solids

1. Clear the area. Notify all persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
3. Shield the source if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry.
5. Notify the Radiation Safety Officer. The RSO will be responsible to supervise clean-up.
6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.

Relative Hazards of Common Nuclides

Spills above these millicurie levels are considered major, below are minor.

Radionuclide	Millicuries	Radionuclide	Millicuries
P-32	10	Tc-99m	100
Cr-51	100	In-111	10
Co-57	100	I-123	10
Co-58	10	I-125	1
Fe-59	10	I-131	1
Co-60	1	Yb-169	10
Ga-67	100	Hg-197	100
Se-75	10	Au-198	10
Sr-85	10	Tl-201	100

Surface Contamination Levels (dpm/100 cm²)

Area	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
Unrestricted & Personal Clothing	200	2,000
Restricted	2,000	20,000

Contact Personnel

Name	Position	Work	Mobile/Pager	Home
	Radiation Safety Officer Technologist			

MCV Campus

V i r g i n i a C o m m o n w e a l t h U n i v e r s i t y

**Office of Environmental
Health & Safety**

Sanger Hall, B2-014
1101 East Marshal Street
P.O. Box 880112
Richmond, Virginia 23298-0112

Phone: 804 828-5877
Fax: 804 828-1167
TDD: 1-800-1120

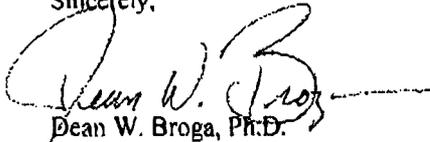
September 5, 2007

To Whom it May Concern:

This is to verify that Drs. Michael Hagan, Olubunmi Abayomi and Mitchell Anscher were approved by the University's Radiation Safety Committee as an authorized user for manual brachytherapy (10 CFR 35.400), pursuant to the training and experience requirements in 10 CFR 35.940. All three are active users of these materials at his point in time (see attached RSC matrix).

Should you have any questions or need any additional information, please contact Mary Beth Taormina in our Radiation Safety section at (804) 828-7097.

Sincerely,



Dean W. Broga, Ph.D.
Director - Office of Environmental Health & Safety
Radiation Safety Officer

Authorized Users VCUHS

Authorized User		35.100	35.200	10 CFR 35.300						35.1000
NRC License #45-00048-17	Approved	Uptake Dilution	Imaging	Sr-89 (Metastron)	Sm-153 (Quadramet)	I-131 CA therapy	I-131 Hyper & CD	I-131 (Bexxar)	Y-90 (Zevalin)	Y-90 (TheraSpheres)
Nuclear Medicine										
Melvin J. Fratkin, M.D.	3/9/89	U	U	U	A	U	U	U	U	U
Paul R. Jolles, M.D.	3/27/92	U	U	U	A	U	U		A	
Karen A. Kurdziel, M.D.	3/22/01	U	U	U	A	U	U		A	

Authorized User		10 CFR 35.400					35.1000	35.600
NRC License #45-00048-17	Approved	I-125 (sealed source)	Pd-103 (sealed source)	Cs-137 (sealed source)	Ir-192 (sealed source)	Y-90 (TheraSpheres)	Sr-90 IVB	Ir-192 HDR
Radiation Oncology								
Christopher R. Johnson, M.D.	1986	U	A	A	A		A	A
Michael P. Hagan, M.D. Ph.D.	1996	U	U	A	U		A	U
Douglas W. Arthur, M.D.	1995	A	A	A	A		U	U
Theodore D. K. Chung, M.D., Ph.D.	9/14/00	A	A	A	A		A	U
Olubunmi K. Abayomi, M.D.	9/13/01	A	A	U	U		U	U
Monica M. Morris, M.D.	9/13/01	A	A	A	A		A	A
Michael G. Chang, M.D.*	6/10/04							A
Laurie Cuttino, M.D.*	8/4/05			A	U			A
Mitchell Anscher, M.D.	12/14/06	A	A	A	A		A	A

Authorized Medical Physicist		35.1000	35.600
NRC License #45-00048-17	Approved	Sr-90 IVB	Ir-192 HDR
Radiation Oncology			
Jeffrey Williamson, Ph.D.	09/08/03	A	A
Nersin Dogan, Ph.D.	09/08/03	A	A
Habeeb Saleh, Ph.D.	02/28/07		A
Mirek Fatyga, Ph.D.	02/28/07		A
Yan Wu, M.S.	08/21/07		A
Dorin Todor, Ph.D.	12/08/05	A	A
Zhong Su, Ph.D.	3/29/07		A

Authorized Nuclear Pharmacist		35.100	35.200	35.300
NRC License #45-00048-17	Approved	Uptake Dilution	Imaging	Therapy
Nuclear Medicine				
Jerry Hirsch, Ph.D.	01/17/95	A	A	A

Last Updated: 8/23/07

Note: "A" indicates authorized and "U" primary user. Any individual who is listed as inactive for 7 years will be removed from the list and required to meet the requirements under Part 35 for re-listing.

Sep. 6, 2007 9:03AM SRMC ADMINISTRATION 8048625948 No. 4464 P. 11/11