

ATTACHMENT 3
CASE 1
PATIENT RELEASE TO HOTEL

The Radiation Safety Officer (RSO) is new since the last inspection and is assisted by 2 staff for training, audits, etc. Survey meters are sent out for calibrations. Since the last inspection, several new nuclear medicine physicians, 1 radiation oncology physician, and 1 medical physicist were approved by the RSC. The permits issued for the nuclear medicine physicians and the radiation oncologist contained mistakes and authorized the users for more uses than their training supported (e.g., oncologist approved for 35.600, even though training only supported 35.300 and 35.400). During the inspection, the licensee confirmed that the physicians only used licensed material for which they had training and revised the permits to more accurately reflect the users training. The licensee also removed "Teletherapy" from all radiation oncologists' authorizations. The documentation reviewed by the RSC for the new medical physicist included the physicist's statement that he had a M.S. in Physics, 1 year of medical physics training at Georgetown, and 1 year of experience at Georgetown. The topics of the medical physics training were not specifically described. In a letter dated August 29, 2007, the licensee provided a copy of his Physics diploma, vendor training certificates while in Ecuador, and generically described his medical physics training under the previous chief clinical physicist. A review of the additional information supported the licensee's approval of the physicist, however, during the exit, the licensee was reminded to clearly document all medical physics training prior to approval of an individual as an AMP.

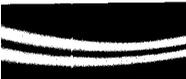
The license includes a license condition for use of the Webster formula when calculating personnel exposures. The Interventional Radiologist involved with sirsphere treatments is the only physician necessitating this calculation to remain below the occupational dose limits.

During the exit, the licensee was reminded to update their financial assurance to address changes to the trustee. In addition, for concerns identified during the inspection, the licensee: (1) revised their return shipment policy for Tc-99m to list the current limited quantity allowance; (2) re-trained nuclear medicine staff on appropriate meter settings for survey instruments; and (3) labeled all radioactive waste and storage containers in nuclear medicine.

The inspector determined that the licensee had released 2 patients to area hotels. In a letter dated August 29, 2007, the licensee provided additional information to support the release. In response to a TAR issued on June 12, 2008, OGC indicated that release to a hotel was not prohibited by the regulations.

2 SLIV violations were identified: 49CFR173.421 - Failure to ensure that excepted packages offered for shipment contained less than the limited quantity amounts (e.g., shipping back 75 mCi of Tc-99m when the LQ was 11 mCi); 20.1904 - Failure to label radioactive waste containers with an estimate of the quantity of radioactivity. The licensee provided their corrective actions in a letter dated August 29, 2007, which included retraining of staff of the amount of licensed material that constitutes limited quantity and properly labeling all waste containers to include the quantity of radioactivity.

Jason D. Dunavant, CHP
Radiation Safety Officer



Georgetown
University
Hospital 

MedStar Health
August 29, 2007

Department of Radiation Safety

Penny Lanzisera
Health Physicist
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406

08-30577-01
03035409/2007001

Dear Ms. Lanzisera

Enclosed is the response to questions that were raised during the inspection on August 9-10, 2007 of Georgetown University Hospital (GUH). You requested this information in the exit interview on August 10, 2007 for Nuclear Regulatory Commission (NRC) License Number 08-~~577~~-01.
30577 nrc

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REGION 1

Additional information on the qualifications for authorized medical physicist Nicolas Recalde is included in Appendix 1. Mr. Recalde has two masters' degrees, a masters of science in physics from the University of South Carolina that was documented on the NRC Form 313A and a masters of science degree in medical physics from Paul Sabatier University in Toulouse, France award in 1998. He also had medical physicist experience in Ecuador starting in 1995. Mr. Recalde has worked as a junior physicist since 1995 except for the four years he was a graduate student at the University of South Carolina (1999 to 2003). Mr Recalde's experience and training includes four years at Georgetown University Hospital 2004-2007, most of which was supervised by the previous chief clinical physicist, Azam Niroomand-Rad, PhD, DABR. In addition, Mr. Recalde has documented at least 22 days of short courses in medical physics in 1998 and 1999. While at GUH, Mr. Recalde participated in at least 100 hours of medical physics lectures that reviewed the Physics of Radiotherapy by Khan. These lectures include reviews of brachytherapy, high dose rate after-loaders, prostate implant and intravascular brachytherapy. Mr. Recalde's qualifications have been reviewed by the American Board of Radiology and he has taken Parts I and II of the Therapy Physics board exams.

Because of concerns raised during the NRC inspection that Mr. Recalde did not meet the qualifications, the Radiation Safety Committee rescinded his approval as an authorized medical physicist for NRC regulated activities. Mr. Recalde and his current employer were notified of this action. This action was taken because Mr. Recalde had

never acted independently as an authorized medical physicist at GUH and thus will limit any impact should the NRC determine that Mr. Recalde is not fully qualified.

In the future, GUH will use the NRC's Licensing Guidance for Using NRC Form 313A Series of Forms. Specifically, documentation will be generated to details for the year of full time training and the year of full time experience.

A review of all inpatient iodine ablation patients in the last two years was made and two patients were identified who were released to hotels after receiving iodine-131 ablation therapy. The documentation for both patients is included in Appendix 2.

One patient completed the GUH iodine ablation questionnaire and indicated that she would be sharing a bathroom at a residential hotel. The decision was made to release this patient when her exposure rate at one meter of not more than 7 mR/h. This patient's exposure rate at discharge was less than 4.9 mR/h. (See Appendix 2, Annex A)

The second patient completed the questionnaire stating that he could comply with all of the guidance for early release at 14.3 mR/h. Additional instruction was provided to him due to his going to a hotel and his having a small child at home. The RSO at the time performed a dose calculation based upon his being below 12 mR/h at one meter at the time of release. (See Appendix 2, Annex B). The dose assessment determined that the maximum dose to any member of the public would be 91 mrem.

An additional dose assessment was made right after the NRC Inspection in August 2007. Using equations B-3, B-4, and B-5 from NUREG 1556, volume 9, a curve fit was made using the initial dose rate and the release dose rate. Using a fast half life of 0.58 days with a fast fraction of 0.95, a slow half life of 7.3 days with a slow fraction of 0.05, an initial reading of 27 mR/h at 15:30 and a release reading of 11.7 mR/h at 09:30 the next day, it was determined that the patient would have checked into the hotel at 15:00 with an exposure rate of approximately 9 mR/h at one meter and with approximately 53 milliCuries of Iodine-131 in his body. It was determined using the model that if the patient checked out of the hotel 45 hours later (the maximum two day stay), his exposure rate would have been approximately 2 mR/h at one meter and would have had approximately 10 milliCuries still in his body.

In a worst case scenario, where the patient laid on his bed for the entire 45 hours of his hotel stay, and an individual in the next room laid on a bed within six feet, the maximum dose to the individual in the next room would have been approximately 52 mrem. Assuming one hour of maid service each day and using equation B-6 from NUREG 1556, volume 9, the worst case scenario for housekeeping would be an external dose of approximately 6 mrem and an internal dose of approximately 23 mrem.

GUH has started screening all ablation patients to ensure that if the patient indicates that they are going to a hotel that they will be held no more than 7 mR/h at one meter until clarification is received from the NRC.

Ms. Nancy Harrison at US Bank Corporate Trust Services was contacted on August 13, 2007. Ms. Harrison stated that she had the originals of the Standby Trust Agreement for GUH and that she would send one of the originals to the NRC. GUH received a copy of a memorandum from US Bank to the NRC Region I indicating that the original had been forwarded to the NRC on August 17, 2007.

A training session was held on August 13, 2007 with the Nuclear Medicine staff to review the proper operation of the Victoreen Ionization Chamber. The training included a review of the different modes of operation and how to recognize the different modes. A practical exercise using a Cs-137 check source was performed to ensure that the Nuclear Medicine staff could properly operate the survey meter.

The training also covered the procedures for properly returning unused radiopharmaceuticals to Cardinal Health's nuclear pharmacy. The training covered the use of the return form and the need to wait two days before returning any unused radioactive material. A review of the radiopharmaceutical return forms has been added to the monthly Nuclear Medicine Audit checklist.

In the Nuclear Medicine Hot Lab, all drawers containing radioactive material were marked as containing radioactive material during the inspection. The radioactive sharps containers were resituated so that they are farther away from Nuclear Medicine Staff working in the hot lab and an additional layer of lead bricks was added to the top of the sharps container shielding. A sign was posted instructing the Nuclear Medicine Staff on proper placement of the radioactive sharps containers. A lead lined container was placed under the sink for disposal of the ventilation atomizers. In addition, lead vinyl shielding was added to the existing steel wall between the waste container and the hot lab sink.

All containers of radioactive waste for decay-in-storage were labeled with an estimate of the activity of the radioactive material in addition to the isotope. In the future, all decay-in-storage containers of radioactive waste will be labeled with an estimated activity.

The Radiation Safety Committee permits were change to reflect that teletherapy is only performed using linear accelerators, and stereotactic radiosurgery is performed using a Cyberknife, and that the uses of radioactive material in nuclear medicine are qualified IAW 35.392, 35.394, and 35.396.

If you have any additional question, please contact me at 202-444-4534, facsimile at 202-444-0069, or e-mail at jdd2@gunet.georgetown.edu.



JASON D. DUNAVANT, CHP
Director, Radiation Safety

PATIENT RADIATION SURVEYS

Patient Name: [REDACTED]

Room No: B3017

G7A Nuclide: I131 Activity: 102.32 ~~100~~ mCi.

Date/Time of Dosing: 01/24/06 ~~01/25/06~~ ¹⁴⁵⁰ *G7A*

Dosing Personnel	Bioassay Dates / (Ok?: Y/N)
[REDACTED]	01/26 / Y
	01/26 / Y
	01/30 / Y
	01/26 / Y
	01/27 / Y

Dose Rate Readings in mrem/h:

- A - One meter from stomach, pt standing erect
- B - Maximum at 30 cm, head to waist*
- C - Doorway at waist level
- D - Adjacent Room No. 16
- E - Adjacent Room No. 18
- F - Hallway (highest value)

* If readings indicate an abnormal localization in the esophagus, throat or mouth, notify the Nuclear Medicine physician. Make survey at the time of dosing.

Date	01/24/06	01/25/06		
<i>G7A</i> Time	1450 1530 h	0925 h		
A mR/h	20 mR	4.9		
B (initial)	250 mR			
C (initial)	10 mR			
D (initial)	I131 Tx			
E (initial)	0.47			
F	220 mR			
Surveyor	Alston, C.	Alston, C.		
Instrument	YSIP 6308	YSIP #6158		

Do not release the patient until the radiation level measured at one meter is not more than **7 millirem/hour** or the value indicated on the attached worksheet (cf.: Regulatory Guide 8.39).

Patient was provided written instructions for limiting doses to others by: C.J. Alston
 Final radiation level at one meter from the patient was 4.9 mrem/h.
 Survey Meter: YSIP S/N: 6155 Calibration Date: 02/23/05
 Patient Released by C.J. Alston Date: 01/25/06

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 BY NRC. NO COPY OF THIS INFORMATION
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Appendix B Annex a

EXHIBIT 1
NUCLEAR MEDICINE DEPARTMENT
INFORMATION CONCERNING HOSPITALIZATION FOR PATIENTS
ADMINISTERED RADIOACTIVE IODINE

The Nuclear Regulatory Commission has concluded that the radioactive iodine that you receive for therapeutic purposes will cause only small radiation exposures to others if you are released from the hospital in accordance with Nuclear Regulatory Commission guidelines. Special precautions are required for women patients nursing infants or small children. Exposures occur mainly if other people remain close to you (less than 3 feet) for long periods of time (at least one hour) during the first few days after you leave the hospital. The Nuclear Medicine Department will make measurements with a radiation detector to determine that you meet Nuclear Regulatory Commission guidelines prior to leaving the hospital.

Normally, these measurements indicate that a patient may be released less than 24 hours after receiving the dose of radioactive iodine. Thus you may only need to be in the hospital for one night. Sometimes, the measurements indicate that a patient does not meet the Nuclear Regulatory Commission's guidelines assuming normal contact and activities with other people. In those circumstances, you may need to remain for a second night. By answering the following questions and agreeing to follow the guidelines, you may be able to be released earlier because of your limited contact with other people.

1. Are you a woman nursing a small child or infant?

Yes ___ No

NOTE: Nursing an infant or small child after receiving radioactive iodine will transfer the radioactive iodine from the mother to the child through the milk. Radioactive iodine ingested by the child will expose the thyroid of the child to potentially harmful levels of radiation. Lifelong medication may be required to prevent serious effects both mentally and physically if the child's thyroid receives a high dose of radiation. **If you are nursing a child, inform Nuclear Medicine personnel and we must reschedule your administration at a later date after you have permanently ceased nursing this child.**

2. Can you take care of yourself except for brief visits and not be in the same room with another person for more than three hours total during each of the first two days?

Yes No ___

If no, briefly explain circumstances: _____

3. Will you be able to maintain distance from other people, including:
- Sleeping alone for at least one night (recommend 3 nights)?
 - Avoiding kissing and sexual intercourse for at least 3 days?
 - Staying at least 3 feet away from people if you will be involved with them for more than an hour a day in the first 3 days?

Yes No

If no, briefly explain circumstances: _____

4. Will you avoid travel by airplane or mass transit for the first day?

Yes No

If no, briefly explain circumstances: _____

5. Will you avoid prolonged travel in an automobile with others for the at least first two days?

Yes No

If no, briefly explain circumstances: _____

6. Will you have sole use of a bathroom for at least two days?

Yes No

If no, briefly explain circumstances: I am living in a one-bed
residential hotel w/ my husband. However he can
stay with friends if necessary. We can do housekeeping
& laundry separately, if necessary.

I have read these guidelines, understand the instructions and agree to avoid contacts in accordance with my answers to items 2 through 6. [Note: If you can not manage at home and avoid close contact, it may be necessary for you to remain in the hospital up to an additional 24 hours.]

Signature: 

Date: 1.23.02

(Patient or other person in accordance with hospital informed consent policy.)

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

*American
 Foreign
 Service
 Association
 JMM
 April, 2007*

EXHIBIT 2
**WORKSHEET FOR DETERMINING ACCEPTABLE DOSE RATES FOR
 RELEASE OF PATIENTS ADMINISTERED RADIOACTIVE IODINE**

I. Regulatory Limit

10 CFR 35.75 permits release of patients if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem.

II. Acceptable methods

Acceptable methods are described in Regulatory Guide 8.39 "Release Of Patients Administered Radioactive Materials."

III. Calculations

Calculations will be based on Equation B-1 from this guide.

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

where

D(t) = Accumulated dose to time t, in rem

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

Γ = Exposure rate constant for a point source, R/mCi x hr at 1 cm

Q₀ = Initial activity at the start of the time interval

T_p = Physical half-life in days

E = Occupancy factor that accounts for different occupancy times and distances when an individual is around a patient

r = Distance in centimeters. This value is typically 100 cm

t = exposure time in days

However the dose rate in R/hr for the effective remaining activity Q_m at time t_m (when a measurement is made) is by the definition of Γ:

$$\frac{dD(t)}{dt} = \frac{\Gamma Q_m}{r^2} \quad \text{or} \quad Q_m = \frac{dD(t)}{dt} \times \frac{r^2}{\Gamma}$$

and since the dose to infinity after the dose rate measurement at time t_m is:

$$D_\infty = \frac{34.6 \Gamma Q_m T_p E (1 - 0)}{r^2}$$

$$\text{Then } D_\infty = (dD/dt) * 34.6 * T_p * E$$

For the purposes of this worksheet:

$D = 500$ millirem

$T_p = 8.08$ days

And the acceptable dose rate is therefore

$dD/dt = 500 / (34.6 * 8.08 * E) = 1.79 / E$ mrem/hour

$E = .25$ or 0.125 depending on the patient circumstances.

IV. Evaluation (Sign for the appropriate dose rate for this administration)

1. The patient has not submitted information about possible contacts with other people, we can assume without further justification the occupancy factor is 0.25. [Reference: Regulatory Guide 8.39 "Release Of Patients Administered Radioactive Materials" and 10 CFR 35.75]

The measured dose rate at 1 meter must be equal to or less than 7 millirem/hour

2. If the patient has submitted information about possible contacts with other people and has answered yes to all questions 2 – 6 of the questionnaire, we can assume the occupancy factor is 0.125. [Reference: Section B.1.2, "Occupancy Factors To Consider for Patient-Specific Calculations," Regulatory Guide 8.39 "Release Of Patients Administered Radioactive Materials".

The measured dose rate at 1 meter must be equal to or less than 14.3 mrem/hr for thyroid patients.

Signature of person making evaluation _____

3. If the patient has submitted information about possible contacts with other people but has answered no to any of the questions 2 – 6 of the questionnaire, the Radiation Safety Officer or Deputy Radiation Safety Officer will make the determination of acceptable dose rate. [Reference: Section B.1.2, Regulatory Guide 8.39 "Release Of Patients Administered Radioactive Materials".

The measured dose rate at 1 meter must be equal to or less than 7 millirem/hour

Basis:

Signature of Radiation Safety Officer _____

John E. Glenn, PhD
Radiation Safety Officer



Georgetown
University
Hospital 

Radiation Safety

June 7, 2006

Radiation Safety Precautions at Home and Elsewhere for Patients Who Have Received Therapeutic Amounts of Radioactivity

Note: Please carefully read and follow the instructions in this document. If you or your health care providers have any questions or concerns regarding the radionuclide therapy you have received, please contact:

Nuclear Medicine Attending Physician
(202) 444-3360
Telephone number

 received a therapeutic dose of **5735 MegaBecquerels (MBq) (155 millicuries (mCi))** of **Iodine-131 Sodium Iodide** at Georgetown University Hospital on June 6, 2006 at 3:30 p.m. and should observe the following radiation safety precautions as follows.

- Avoid close contact with (less than 1 meter, or 3 feet, away from) pregnant women and children until **June 9, 2006**.
- Do not hold or embrace children for more than **10 minutes** a day until **June 13, 2006**.
- From **June 13, 2006** until **June 20, 2006** you should avoid very close contact with children for longer than an hour but may spend 3 to 4 hours per day at 3 feet from children.
- After **June 21, 2006** you may resume very close contact with children for 3 hours a day.
- Do not sleep in the same bed with your sleeping partner until **June 9, 2006**.
- Beginning **June 7, 2006**, there are no restrictions on public transportation for periods up to 3 hours.

MedStar Health

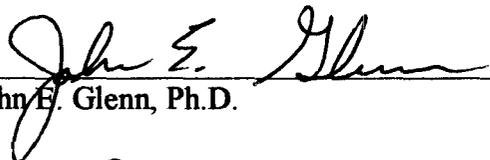
3800 Reservoir Road, NW, LL 17 PHC, Washington, DC 20007-2113
phone: 202 444 4049 • fax: 202 444 0069 • email: jeg43@gunet.georgetown.edu

Appendix 2, Annex b

In addition, the following precautions should be observed until **June 9, 2006**:

1. To the extent that is reasonable, try to remain far away from individuals around you.
2. You should otherwise observe good personal hygiene and may shower, bathe, shave, etc as you normally would, rinsing the shower stall, tub, or sink thoroughly after use.
3. Wipe up any spills of urine, saliva, and/or mucus with disposable paper toweling or tissues, dispose of the paper in the toilet, and flush the toilet two times.
4. While at the hotel, rinse plates, bowls, spoons, knives, forks, and cups. If disposable utensils can not be rinsed or flushed, refer to item 8.
5. Rinse the sink thoroughly after use (tooth brushing) and wipe the fixtures with disposable paper toweling, disposing of the paper toweling in the toilet, and flushing the toilet two times.
6. Store and launder your soiled/used clothing separately from those of the rest of your household, running the rinse cycle two times at the completion of machine laundering.
7. Do not share food or drinks with anyone.
8. Any disposable items that come into contact with body fluids and can not be flushed down the toilet should be placed in a plastic bag and held. The bag should be held for 3 weeks before going into the home trash or brought to the Georgetown University Hospital Radiation Safety Office for disposal. Phone: 202-444-4657. Office: Gorman 2047.

After **June 9, 2006**, contamination should not be an issue.



John E. Glenn, Ph.D.

Date: June 7, 2006

Fast HL	0.6
Slow HL	7.3
fast frac	0.95
slow Frac	0.05
Init Reading	27

Occupancy	Dose at 1	
Factors	meter	
	0.5	364
	0.25	182
	0.125	91

t	X(t)	Infinity Dose(.25)	Infinity Dose (0.125)	Infinity Dose (0.125) 1 foot	Infinity Dose (1 hour) 1 foot
0.00	27	1704.9	852.5	7672.1	2557
0.75	12.044	760.5	380.2	3422.2	1141
1.00	9.309	587.8	293.9	2645.2	882
2.00	3.6626	231.3	115.6	1040.7	347
3.00	1.8176	114.8	57.4	516.5	172
4.00	1.1762	74.3	37.1	334.2	111
5.00	0.9195	58.1	29.0	261.3	87
6.00	0.7889	49.8	24.9	224.2	75
7.00	0.7025	44.4	22.2	199.6	67
8.00	0.6342	40.0	20.0	180.2	60
9.00	0.5753	36.3	18.2	163.5	54
10.00	0.5227	33.0	16.5	148.5	50
11.00	0.4752	30.0	15.0	135.0	45
12.00	0.4321	27.3	13.6	122.8	41
13.00	0.393	24.8	12.4	111.7	37
14.00	0.3574	22.6	11.3	101.6	34

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Yes ___ No

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2. Can you take care of yourself except for brief visits and not be in the same room with another person for more than three hours total during each of the first two days?

Yes No ___

If no, briefly explain circumstances: _____

3. Will you be able to maintain distance from other people, including:
- Sleeping alone for at least one night (recommend 3 nights)?
 - Avoiding kissing and sexual intercourse for at least 3 days?
 - Staying at least 3 feet away from people if you will be involved with them for more than an hour a day in the first 3 days?

Yes No

If no, briefly explain circumstances: _____

4. Will you avoid travel by airplane or mass transit for the first day?

Yes No

If no, briefly explain circumstances: _____

5. Will you avoid prolonged travel in an automobile with others for the at least first two days?

Yes No

If no, briefly explain circumstances: _____

6. Will you have sole use of a bathroom for at least two days?

Yes No

If no, briefly explain circumstances: _____

I have read these guidelines, understand the instructions and agree to avoid contacts in accordance with my answers to items 2 through 6. [Note: If you can not manage at home and avoid close contact, it may be necessary for you to remain in the hospital up to an additional 24 hours.]

Signature: _____

Date: 6/6/06

(Patient or other person in accordance with hospital informed consent policy.)

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

Form 0.62

6/28/02

RADSHARE\Section 0 - Forms\Nuc Med 0.6 thru 0.8\Form 0.62_I-131_Patient_Release_File3.6