Jason D. Dunavant, CHP Radiation Safety Officer

Department of Radiation Safety

Georgetown University Hospital 🞬

MedStar Health August 29, 2007

08-30577-01 03035409/2007001

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

Dear Ms. Lanzisera

31 PM 12: Enclosed is the response to questions that were raised during the inspection on 91 August 9-10, 2007 of Georgetown University Hospital (GUH). You requested this information in the exit interview on August 10, 2007 for Nuclear Regulatory Commision (NRC) License Number 08-577-01.

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 Toulose, France award in 1998. He also had medical physicst 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 Recalde did not meet the qualifications, the Radiation Safety Committee rescinded his approval as an authorized medical physicist for NRC regulated activities.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 in 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 below12 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 milliCuires 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 <u>jdd2@gunet.georgetown.edu</u>.

JASON D. DUNAVANT, CHP Director, Radiation Safety



Tet ft be known to all

That the Board of Trustees by virtue of authority vested in it by the State of South Carolina upon recommendation of the Jaculty of the **Graduate School**

has conferred upon

Nicolus Aldunate Recalde

the degree of Master of Science Bhysics

together with all the rights, honors, privileges, and responsibilities to that degree appertaining.

Given at Columbia, South Carolina this 9th day of August in the year of Our Lord two thousand and three and in the two hundred and second year of the University's founding.



Appondix 1

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Nikolás Recalde

has successfully completed the

BRAINSCAN XL CLINICAL TRAINING AT CHARITÉ HOSPITAL IN BERLIN

29th Sept. till 2nd October, 1998, 8 hours a day

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Varian oncology systems customer support

Awards this

Certificate of Attendance Nicolas⁶ Recalde

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May 11, 2004

Appendix 2 Annexa

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.

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 \times 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 <u>No</u> 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 \succeq 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 - ban <u>vesiden that hated of my husbard</u>. However the ca <u>stay with freeds of newsong</u>. We can do how scheeping *i laundry separately*, if newsong.

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.]

Signal

Form 0.62

Date: 1. 23. 6

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

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EXHIBIT 2

WORKSHEET FOR DETERMING ACCEPTABLE DOSE RATES FOR RELEASE OF PATIENTS ADMINISTERED RADIOACTVE 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-Ifrom this guide.

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

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

 Q_0 = Initial activity at the start of the time interval

Tp = 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 :

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

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

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

Then
$$D_{\infty} = (dD/dt)^{*}34.6^{*}T_{p}^{*}E$$

Form 0.62 RADSHARE\Section 0 - Forms\Nuc Med 0.6 thru 0.8\Form 0.62_I-131 Patient Release File3.6

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)
- 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

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 $\underline{\nearrow}$ millirem/hour Basis:

Signature of Radiation Safety Officer

John E. Glenn, PhD Radiation Safety Officer

Radiation Safety

June 7, 2006

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

Georgetown

University

Hospital 🞬

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

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.

Appendix 2, Annex b

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

MedStar Health

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 <u>hotel</u>, 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.

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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 Z. June John F. Glenn, Ph.D. Date: June 7, 2006

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slow Frac	0.05			0.125	91
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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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EXHIBIT 1 NUCLEAR MEDICINE DEPARTMENT INFORMATION CONCERNING HOSPITALIZATION FOR PATIENTS ADMINISTERED RADIOACTIVE IODINE

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Yes No X

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:

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- 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 <u>V</u> 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 RADSHARE\Section 0 - Forms\Nuc Med 0.6 thru 0.8\Form 0.62_I-131_Patient_Release_File3.6